United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-019
September 2000

Reregistration Eligibility Decision (RED)

Etridiazole (Terrazole®)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 4, 2000

RE: Reregistration Eligibility Decision for Etridiazole (Terrazole®)

Dear Recipient:

Attached is the Reregistration Eligibility Decision for Etridiazole (Terrazole®). You will note that in the text of the document, vapor pressure of the dry formulations is identified as a data gap. However, the Agency has reevaluated the need for this data in light of other data that are being requested, and decided not to require the vapor pressure study. Consequently, vapor pressure data are not listed in the accompanying Data Call-In.

If you have any questions, please free to contact me at 703/308-8065.

Sincerely,

Lois Rossi, Director
Special Review and Reregistration Division

Page 56 of Human Health Risk Assessment

As etridiazole is used only as a soil-incorporated fungicide and seed treatment, there are a limited number of use patterns. It is used for at-planting in-furrow crop soil treatments (only cotton at this time); as a soil treatment, either by drenching or addition to potting soil, for ornamentals and interiorscapes; on ornamental turf and golf course fairways, greens, and tees, either by spray or broadcast application; and as a seed treatment, applied in either large commercial facilities, or at the farm. Total annual use of etridiazole is estimated by BEAD at approximately 75,000 lb ai (these estimates are approximate and therefore totals by crop may not exactly concur with overall total cited). An estimated 42,500 lbs ai of etridiazole is applied to cotton at planting, with a typical application rate of about 0.17 lbs ai/acre. About 28,000 lbs ai of etridiazole are believed to be applied by nurseries; mainly to control for root diseases (USDA, NAPIAP Report, 1-CA-96). About 5,000 lbs ai of etridiazole are also applied annually to golf courses. All of the dusts are formulated by one company, Gustafson, for seed treatment. Only a limited amount of seed treatment (less than 1% of the market per BEAD) is done in this country using this active ingredient, but all active labels are evaluated for handler and post-application health risks. Etridiazole is registered for use as a seed treatment on barley, beans/peas, peanuts, corn, safflower, sorghum, soybeans and wheat; of these crops, peanuts have received a modest amount of treatments with etridiazole.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessment for the thiazole pesticide etridiazole (Terrazole®). Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of etridiazole. The EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of etridiazole, and its associated human health and environmental risks. The enclosed "Reregistration Eligibility Decision for Etridiazole," which was approved on September 27, 2000, contains the Agency's decision on the individual chemical etridiazole.

A Notice of Availability for this Reregistration Eligibility Decision (RED) for etridiazole is published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See http:www.epa.gov/pesticides.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. The U.S. Department of Agriculture held a teleconference on May 11, 2000, with interested stakeholders and provided the Agency with input on etridiazole usage and occupational practices. The human health and environmental risk assessments were placed in the public docket and an invitation for public comment was announced in the *Federal Register* on June 28, 2000. In addition, a second conference call was held September 13, 2000 during which the Agency presented a summary of the risk assessment and the results of the risk management decision for the registrants, USDA, and other stakeholders.

Please note that the etridiazole risk assessment and the attached RED concern only this particular chemical. Etridiazole is a member of the thiazole class of fungicides. While current data are limited,

EPA has evidence that compounds within a class may share a common mechanism of toxicity. At this time, the Agency does not have sufficient data concerning common mechanism issues to determine whether or not etridiazole shares a common mechanism of toxicity with other substances, including other thiazoles or other probable human carcinogens. Therefore, for the purposes of this risk assessment, the Agency has assumed that etridiazole does not share a common mechanism of toxicity with any other chemicals.

End-use product labels should be revised by the manufacturer to adopt the changes set forth in Section V of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Robbi Farrell, at (703) 308-8065. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Venus Eagle at 703/308-8045.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision

for

Etridiazole

List A
Case 0009

Table of Contents

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration.
EP	End-Use Product
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MUP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System

Glossary of Terms and Abbreviations

NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PAD	Population Adjusted Dose
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of etridiazole. This document also presents the Agency's tolerance reassessment decision for etridiazole, which includes the consideration of risk to infants and children for any potential dietary, drinking water, dermal, inhalation or oral exposures. The Agency made its reregistration eligibility determination and tolerance reassessment decision based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that most currently registered uses of etridiazole are eligible for reregistration, provided specified changes are made to the label. Golf course fairway use will be removed from product labels due to ecological and drinking water risks, pending submission and evaluation of additional exposure and toxicity data.

Use Summary

Etridiazole is a fungicide registered for use as a seed treatment on the following crops: barley, beans, corn, cotton, peanuts, peas, sorghum, soybeans, safflower, and wheat. It is also registered for use on cotton for in-furrow application at planting, on ornamental plants and shrubs by horticultural nurseries, on non-bearing citrus and non-bearing coffee, and for golf course fairways, tees and greens. In addition, seven states hold Special Local Need [Section 24(c)] registrations for use on tobacco transplants. There are no registered homeowner uses. EPA estimates that approximately 84,000 pounds of active ingredient are used annually, about 50% of which is applied to cotton, 25% used by nurseries on ornamentals, and 5% applied to golf course turf.

Carcinogenicity Classification

Etridiazole is classified as a Group B2 carcinogen (probable human carcinogen), based on multiple tumor types in the liver, bile duct, mammary gland, thyroid and testes in rats. The Agency utilized a low-dose (Q_1*) approach to characterize human cancer risk.

Dietary Risks

Acute, chronic and cancer dietary risk from food are not of concern. Acute and chronic (non-cancer) risks from etridiazole in groundwater and surface water are also not of concern. Aggregating food and water risks results in cancer risks from surface water that are of concern for the general population based on modeled estimates of environmental concentrations of etridiazole in surface water from use on golf course tees, greens and fairways.

Worker Risks

Risks for occupational handlers of etridiazole are of concern for some scenarios. The Agency has risk concerns for occupational handlers loading/applying liquid for commercial seed treatment, loading/applying granules, mixing/loading/applying wettable powders, and dispersing granules by hand. Short- and intermediate-term risks are of concern for these scenarios, as are cancer risks. Long-term handler exposures are not expected. In some cases, the calculated risks can be mitigated with additional protective measures such as engineering controls. However, for some scenarios, engineering controls are not feasible.

Occupational postapplication scenarios assessed for etridiazole include greenhouse or nursery workers handling treated potting soil, golf course workers engaged in turf maintenance, and farmers handling treated seed for planting. Postapplication exposure to etridiazole during harvesting or other late-season activity is not expected since it is applied to cotton in-furrow only at the time of planting. There is potential for short- and intermediate-term postapplication exposure to etridiazole residues for workers involved in turf maintenance, handling treated seed, and handling treated potting soil. Long-term postapplication exposure could occur for greenhouse/nursery workers handling treated potting soil. The only postapplication exposure scenario with risks of concern to the Agency is handling treated potting soil, which has cancer risks of 2.9×10^{-5} after 12 hours, which is the current restricted entry interval (REI).

Non-occupational Risks

The only exposure scenario for non-occupational risk is exposure of golfers to treated golf course turf. Due to the volatility of etridiazole, this exposure is expected to be negligible.

Ecological Risks

Etridiazole use on golf course turf is a concern given the relatively high application rates for turf and the likelihood of golf course runoff to move toward surface water.

Acute risks for birds, mammals, fish, aquatic invertebrates and aquatic plants at the typical application rates for golf course turf are of concern. Chronic risks are a concern for birds and aquatic organisms at the typical application rate for turf. Chronic effects seen in laboratory studies include significant reproductive effects in birds and limited growth in fish. No acceptable chronic mammalian data were available, so chronic risks for mammals could not be assessed. Available data indicate that the degradate 3-dichloromethyl-5-ethoxy-1,2,4-thiadiazole (3-DCMT) is highly toxic to aquatic organisms.

Cumulative Risk

FQPA requires that the Agency consider the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." At this time, the Agency does not have sufficient data concerning common mechanism issues to determine whether or not etridiazole shares a common mechanism of toxicity with other substances, including other thiazoles or other probable human carcinogens. Therefore, for the purposes of this risk assessment, the Agency has assumed that etridiazole does not share a common mechanism of toxicity with any other chemicals.

More detailed information can be found in the technical supporting documents for etridiazole referenced in this reregistration eligibility decision document. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page at *www.epa.gov/pesticides*, and in the Public Docket.

Summary of Mitigation

To address drinking water risks associated with estimated surface water concentrations resulting from the use of etridiazole on golf course tees, greens and fairways, the registrant has agreed to immediately remove fairway use from product labels. The registrant has agreed to provide additional water data to refine exposure estimates. In addition, a repeat cancer study in a second species is required to more fully characterize carcinogenicity. Should either study result in estimates of risk greater than or equal to those currently estimated, the registrant has agreed to voluntarily cancel the use on fairways. If the additional water data and the second carcinogenicity study together result in risk estimates that are not of concern, fairway use may be returned to product labels.

Pesticide handler risks will be mitigated by a combination of reduced rates and frequency of application, increased personal protective equipment, use of engineering controls, deletion of some use sites, cancellation of the flowable concentrate formulation, cancellation of the granular product registered for golf course use, and elimination of several hand-held application methods. Specifically, the registrants have agreed to the following mitigation measures:

1. Use on fairways will be removed from product labels immediately.
2. The maximum application rate, maximum amount applied per season and frequency of application to golf course tees and greens will be reduced.
3. The granular formulation registered for use on golf course turf will be voluntarily cancelled.
4. Application by power dust blower, belly grinder, push-type spreader and by hand dispersal will be deleted.
5. An organic-vapor respirator will be used for all handlers, except for in-furrow application to cotton or when a closed system is used.
6. Closed systems will be used for seed treatment.
7. The dry flowable concentrate formulation will be voluntarily cancelled.

8. Application rates for treatment of potting soil with the granular formulation will be reduced.

In addition, confirmatory product chemistry, residue, toxicity, and exposure data are required.

I. Introduction

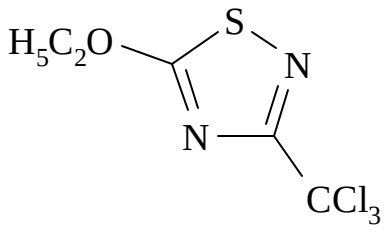
The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

FQPA requires that the Agency consider the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency is examining whether and to what extent some or all organophosphorous and carbamate pesticides may share acetylcholinesterase inhibition as a common mechanism of toxicity. Similarly, the Agency is examining whether and to what extent some or all pesticides that may be carcinogens may also share a common mechanism of toxicity. Current information on the common mechanism of toxicity for thiazoles is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other thiazoles or human carcinogen chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that etridiazole does not share a common mechanism of toxicity with other thiazoles or human carcinogen chemicals.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of etridiazole, including the consideration of risk to infants and children for any potential food, drinking water, dermal, inhalation or oral exposures, and cumulative effects as stipulated under the FQPA for tolerance reassessment. In an effort to simplify the RED, the information presented herein is summarized. More detailed information can be found in the technical supporting documents for etridiazole referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page at *www.epa.gov/pesticides*, and in the Public Docket. The document consists of six sections. Section I is the introduction. Section II provides a profile of the use and usage of etridiazole, and its regulatory history. Section III gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV presents the reregistration eligibility and risk management decisions. Section V summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Chemical Identification



Etridiazole is a reddish-brown liquid with a boiling point of 95° C at 1 mm Hg, specific gravity of 1.5, and octanol/water partition coefficient (K_{ow}) of 2.344×10^3. Etridiazole has a water solubility of ~100 ppm at 25° C, and is soluble in acetone, carbon tetrachloride, ethanol, ether, and xylene. Etridiazole hydrolyzes with acids and bases.

!	**Common Name:**	Etridiazole
!	**Chemical Name:**	5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole
!	**Chemical Family:**	Thiazole
!	**CAS Registry Number:**	2593-15-9
!	**OPP Chemical Code:**	084701
!	**Empirical Formula:**	$C_5H_5Cl_3N_2OS$
a.	**Vapor Pressure:**	1.1×10^{-2} mm Hg at 25° C
!	**Trade Name:**	Terrazole®, Banrot®, Koban®, Truban®, Terraclor®, 4-Way®, Terra-Coat L-205-N®
!	**Basic Manufacturer:**	Uniroyal Chemical Company

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the uses of etridiazole eligible for reregistration is contained in Appendix A.

Type of Pesticide
Etridiazole is a soil fungicide.

Use Sites
Etridiazole is registered for use as a seed treatment on the following crops: barley, beans, corn, cotton, peanuts, peas, sorghum, soybeans, safflower, and wheat. It is also registered for use on cotton for in-furrow application at planting. In addition, etridiazole is registered for use on various ornamental plants and shrubs by horticultural nurseries, non-bearing citrus, non-bearing coffee, and for golf course fairways, tees and greens. Etridiazole is not registered for use on domestically grown tomatoes, but it is used on imported tomatoes. There are no registered homeowner uses.

Seven states (Kentucky, Tennessee, North Carolina, South Carolina, Virginia, Ohio, and Indiana) hold special local need registrations of Terrazole 35% Wettable Powder for use on tobacco. These registrations were granted during the period March through June, 2000. Risks associated with this use site have not been explicitly considered in this risk assessment and reregistration eligibility decision. However, the Agency believes that the occupational risks from this use are within the range of those considered in this risk assessment and are addressed by mitigation agreed upon by the registrant. This use does not contribute to dietary exposure.

Target Pests
Damping-off, root rot, and stem rot caused by *Pythium and Phytophthora*

Formulation Types Registered
Etridiazole is formulated as dusts, granules, wettable powders, flowable concentrates and emulsifiable concentrates. End-use products are sold in the U.S. under the trade names Terrazole®, Terraclor®, Temik® Brand TSX, Banrot®, Koban®, PCNB+ Liquid Seed Treater®, 4-Way Peanut Seed Protectant®, Terra-Coat® L-205N and Truban®.

The PCNB+®, 4-Way®, Terra-Coat®, Banrot® and Terraclor® products contain varying amounts of PCNB, thiophanate-methyl, maneb, and captan. Furthermore, Temik® Brand TSX contains PCNB and aldicarb; Terraclor SuperX® with Di-Syston® EC contains PCNB and disulfoton.

Method and Rates of Application
Mixing equipment for larger operations includes mechanically agitated tanks, and automated metered pumps. For smaller operations, a seed box or hopper box may be used. Application equipment includes planters with spray attachments, boom sprayers, smaller sprayers attached to tractors, all-terrain vehicles or mowers, portable strap-on spreaders, push-type spreaders, hand dispersal, power dust blowers, chemigation and low- or high-pressure hand-held spray wand.

Use rates vary widely depending on the crop/target, as follows:

For in-furrow crop treatment: 0.13-0.38 lbs ai/per acre (ai/A)
For soil drench treatment:
Typical: 6 oz. ai/1000 sq. ft. or 16.3 lbs ai/A
Range (minimum and maximum label rates): 1.5 to 17.5 oz ai/1000 sq. ft. (4.1 to 47.6 lbs ai/A)
For potting soil treatment : 1.1 oz ai/cubic yard (typical)
For golf course turf: 0.7 to 2.8 oz ai/1000 sq. ft. (1.9-7.6 lbs ai/A) up to annual maximum total of 19 lbs ai/A
Seed treatment: 0.0078-0.0625 lbs ai/100 lbs seed
For tobacco transplant float beds: 0.7 oz. ai/100 gallons water

C. Estimated Usage of Pesticide

Table 1 summarizes the best available estimates for the pesticide uses of etridiazole. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Table 1. Etridiazole Usage Summary

Crop	Lbs. Active Ingredient Applied (Wtd. Avg.)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wtd. Avg.)[1]
Agricultural Uses:			
Citrus	0	<1%	0.2%
Coffee	no data	<1%	0.0%
Cotton	43,000	4.2%	2.1%
Beans/Peas	0	<1%	0.0%
Corn	1,000	<1%	0.0%
Peanuts	5,000	2.0%	0.3%
Safflower (Other Crops)	0	<1%	0.0%
Sorghum	0	<1%	0.0%
Soybeans	2,000	<1%	0.0%

Crop	Lbs. Active Ingredient Applied (Wtd. Avg.)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wtd. Avg.)[1]
Wheat, Winter	0	<1%	0.0%
Turf:			
Golf Course Greens, Tees, Fairways	5,000	4.3%	2.9%
Nursery and Greenhouse Ornamentals:			
Container Ornamentals	22,000	1.2%	0.9%
Greenhouse	6,000	18.4%	14.3%

[1]Wtd Avg (Weighted average): the most recent years and more reliable data are weighted more heavily.

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1996.

Calculations of the above numbers may not appear to agree because they are displayed as rounded:

- to the nearest 1000 for lb. ai (Therefore 0 = < 500)
- to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

SOURCES: EPA data (1987-1996), USDA/NASS (1990-1996), California (1993-1995)

D. Regulatory History

Etridiazole (Terrazole®) was initially registered as a pesticide in 1962 by Uniroyal Chemical Company. A Registration Standard for etridiazole was issued in September 1980 (NTIS #PB81-126716). The Registration Standard summarized available data supporting the reregistration of products containing etridiazole. The Registration Standard also required the submission of product chemistry, toxicological and ecological effects data. Data Call-In notices were issued on June 24, 1992, February 18, 1993, and October 13, 1995, and required the submission of product chemistry, toxicity, ecological effects and fate, residue chemistry, and exposure data.

In an effort to promote transparency of the reregistration process and understanding of regulatory decisions, the Agency, in cooperation with the U.S. Department of Agriculture (USDA), modified the reregistration process. This modified process provides opportunities for stakeholders to ask questions about and provide input to the risk assessment and risk mitigation strategies, via conference calls and other formats. Consistent with this process, USDA held a conference call on May 11, 2000, with interested stakeholders (i.e., growers, commodity groups, land grant universities, and others) to discuss the basis of the calculated risks of etridiazole, and the Agency's resultant risk concerns. Information obtained from users and growers during the call, such as etridiazole usage and occupational practices, are reflected in this RED. The human health and environmental risk assessments for etridiazole were

placed into the public docket with an invitation for public comment, as published in the *Federal Register* on June 28, 2000.

A conference call was held on September 13, 2000 to summarize the results of the risk assessment and risk management process for the registrants, USDA, growers and other interested stakeholders.

III. Summary of Etridiazole Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for the thiazole pesticide etridiazole, as presented fully in the documents: *Human Health Risk Assessment for Etridiazole,* June 6, 2000, *Revised Toxicology Chapter of the Reregistration Eligibility Division,* September 13, 2000, *Environmental Fate and Effects Division Risk Assessment for the Reregistration Eligibility Decision on 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole (Etridiazole),* May 22, 2000 and *Terrazole: Refined Tier I Chronic Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment,* May 26, 2000.

The purpose of this decision document is to summarize the key features and findings of this risk assessment in order to help the reader better understand the conclusions reached in the assessment. While the risk assessments and related addenda are not included in this document, they are available on the Agency's web page at *www.epa.gov/pesticides*, and in the OPP Public Docket.

A. Human Health Risk Assessment

1. Toxicity of Etridiazole

The toxicity database for etridiazole is incomplete, and contains no acceptable subchronic studies for use in risk assessment. Data gaps for etridiazole also include a multigeneration reproduction study in rats, a chronic toxicity study in dogs, and a cancer study in mice that meet chronic toxicity test guidelines. These studies have been previously submitted but do not meet current guideline requirements for a food-use chemical. In addition, there is insufficient data to assess the neurotoxic potential of etridiazole. However, additional studies (i.e. delayed neurotoxicity study in the hen, acute neurotoxicity study, subchronic neurotoxicity study and/or developmental neurotoxicity study) are not required at the present time because there is no evidence of neurotoxicity in the available guideline toxicity studies. These studies are placed in reserve status pending submission and evaluation of a repeat multigeneration reproduction study in rats and a chronic toxicity study in dogs.

No quantitative or qualitative evidence of increased susceptibility in rats or rabbits was observed following pre- and/or postnatal exposure to etridiazole. There is no evidence of neurotoxicity in the available guideline toxicity studies.

Available chronic toxicity data indicate that the primary target for toxicity is the liver following chronic exposure to etridiazole in rats. At 640 ppm (30.43 mg/kg/day in males, 38.45 mg/kg/day in females), systemic toxicities observed in the 2-year rat carcinogenicity study included decreased body weight gain in females, increased absolute and relative liver weight in males, hepatocytomegaly in males, spongiosis hepatis in males, clear, basophilic, and eosinophilic hepatocellular alterations in both sexes, hepatic centrilobular pigmentation in females, cholangiectasis in females, renal tubule cell karyomegaly in males and females and testicular interstitial cell hyperplasia in males. In a two-year, non-guideline chronic toxicity study with dogs, systemic toxicities in both sexes manifested as increased serum aspartate transferase (SGOT) and serum alkaline phosphatase (ALK;SAP) activity, increased relative liver weights, liver pathology consistent with cholestatic hepatis with secondary bile nephrosis and increased prothrombin time at a dose level of 25 mg/kg/day.

Etridiazole was classified by the Agency's Health Effects Division Cancer Peer Review Committee (CPRC) as a Probable Human Carcinogen. This classification is based on the following factors: (i) occurrence of multiple tumor types in male and female rats (tumor sites noted were the liver, bile duct, mammary gland, thyroid, and testes) including the induction of a rare bile duct tumor (cholangiocarcinoma), and (ii) non-neoplastic lesions observed in similar target organs that lend support to the association of etridiazole exposure with the induction of tumors; increased absolute and relative liver weight (males), hepatocytomegaly (males); clear, basophilic, and eosinophilic cellular alterations (males and females); cholangiectasis (females); centrilobular pigmentation (females); spongiosis hepatis of the liver (males); and testicular interstitial cell hyperplasia (males) and (iii) positive mutagenicity data. The carcinogenicity study in mice was determined to be unacceptable and not adequate for assessment of the carcinogenic potential of etridiazole in this species. A new study is required. The CPRC calculated a unit risk or Q_1*, of 3.33×10^{-2} $(mg/kg/day)^{-1,}$ based on the occurrence of thyroid follicular cell combined adenomas/carcinomas in male rats.

Etridiazole induced genotoxic responses in several mutagenicity assays and is considered a mutagen. Positive responses occurred in a gene mutation assay in *Salmonella typhimurium*, in the *in vitro* cytogenetics assay in Chinese hamster ovary cells, and in the two *in vitro* sister chromatid exchange assays in Chinese hamster ovary cells.

2. Dietary Toxicity

A brief overview of the toxicity studies used for endpoints in the dietary risk assessment is outlined in Table 2. Further details on the toxicity of etridiazole can be found in the June 6, 2000 *Human Health Risk Assessment* and the *Revised Toxicology Chapter of the Reregistration Eligibility Decision*, September 13, 2000.

Table 2. Summary of Etridiazole Dietary Toxicity Endpoints

Exposure Scenario	Dose (mg/kg/day)	Endpoint/Rationale	Study
Acute Dietary (Females 13-50)	NOAEL=15 UF=100 FQPA SF=1	Reduced fetal body weights, decreased viability, and external and skeletal malformations/variations at the LOAEL of 45 mg/kg/day. The skeletal malformations/ variations (missing sternebrae and tail defects) are presumed to occur after a single exposure (dose) and thus are appropriate for acute risk assessment. Since the selected NOAEL is based on a developmental endpoint, it is applicable only to the population subgroup, females 13-50 years old.	Developmental Toxicity - Rabbit MRID 0010499
	Acute RfD = 0.15 mg/kg Acute PAD = 0.15 mg/kg		
Acute Dietary (General Population)	An appropriate endpoint attributable to a single exposure (dose) was not identified in oral toxicity studies (including the developmental toxicity studies in rats and rabbits) that is applicable to subpopulations other than females of childbearing age (13-50 years old).		
Chronic Dietary	NOAEL=4.8 UF=300 FQPA SF=3	Increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis at the LOAEL of 30.43 mg/kg/day. The uncertainty factor includes 10x for interspecies extrapolation, 10x for intraspecies variation, and 3x applied under FIFRA for toxicology data gaps.	Carcinogenicity - Rats MRID 40747901
	Chronic RfD = 0.016 mg/kg/day Chronic PAD = 0.005 mg/kg/day		
Chronic (Cancer) Dietary	**Group B2 chemical - Probable human carcinogen - Q_1^* = 3.33 x 10^{-2} $(mg/kg/day)^{-1}$** in human equivalents [converted from animals to humans by use of the (mg/kg body weight)$^{\frac{2}{3}}$ cross species scaling factor].		Carcinogenicity - Rats MRID 40747901

a. Acute Dietary Endpoint

For females 13-50 years of age, the NOAEL of 15 mg/kg/day was established based on reduced fetal body weight, decreased viability and external and skeletal malformations/ variations in the rabbit developmental toxicity study observed at the LOAEL of 45 mg/kg/day. Because these effects occurred *in utero*, they are applicable only to females 13-50 years of age. Based on available acute toxicity studies, no other endpoints identified were attributable to a single dose. Thus, the only acute dietary hazard is for females 13-50 years of age, and so acute dietary risk was assessed only for this population subgroup.

b. Chronic (Non-Cancer) Dietary Endpoint

The NOAEL of 4.8 mg/kg/day was established based on increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis observed in a carcinogenicity study in rats at the LOAEL of 30.43 mg/kg/day. The Agency determined that the two-year chronic toxicity study in dogs previously used to establish the chronic RfD does not meet the current guideline requirements. Due to the numerous deficiencies observed as a result of the age of this chronic toxicity study (1966-1969), it is not adequate for establishing the RfD. Consequently, the two-year rat carcinogenicity study was selected for this exposure scenario. A FIFRA uncertainty factor of 3x was used in the chronic dietary risk assessment due to this data gap.

c. Chronic (Cancer) Dietary Endpoint

A linear low-dose approach (Q_1*) was used to characterize human health risk. The unit risk, or Q_1*, based on the occurrence of thyroid follicular cell combined adenomas/carcinomas in male rats, is 3.33 x 10^{-2} $(mg/kg/day)^{-1}$ in human equivalents. Results of a carcinogenicity study in mice were equivocal due to deficiencies in the study design. The Agency is requiring a new carcinogenicity study in mice. In spite of the poor quality of the mouse study, the presence of gross and histopathological lesions in the lungs indicates a concern for possible carcinogenicity in a different organ in a different species.

3. FQPA Safety Factor

Etridiazole lacks an acceptable multigeneration reproduction study which could identify potential reproductive effects following pre-/postnatal exposure to etridiazole. However, the FQPA Safety Factor Committee concluded that the 10x safety factor could be reduced to 3x for the following reasons:

1) there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity studies in rats and rabbits;
2) although the multi-generation reproduction study in rats was determined to be an unacceptable guideline study and not adequate for regulatory purposes by the Hazard Identification Assessment Review Committee, it is noted that the observed offspring effects in this study occurred only at a treatment level which resulted in parental toxicity; and
3) adequate data are available or conservative modeling assumptions are used to assess the potential for dietary (food and drinking water) exposure to infants and children.

The FQPA safety factor is applicable to chronic dietary risk assessment for all population subgroups since there is uncertainty due to the data gap for the two-generation reproduction study in rats which could identify potential reproductive effects. The FQPA safety factor does not apply to acute dietary risk assessment since no increased susceptibility was demonstrated following *in utero* exposure, and because the multi-generation reproduction study in rats is not expected to provide information on the potential for adverse effects occurring after a single exposure (dose).

4. Hazard Determination

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA safety factor (SF). The RfD is an estimated level of daily exposure to a pesticide residue which, over a 70-year human life span, is believed to have no significant deleterious effects. Where the FQPA SF has been removed (equivalent to 1x), the acute or chronic RfD is equivalent to the acute or chronic PAD. In the case of etridiazole, the FQPA SF has been removed (equivalent to a factor of 1x) for the acute dietary assessment. For the chronic dietary risk assessment, the RfD includes a 3x uncertainty factor applied under FIFRA due to the lack of a chronic oral toxicity guideline study in dogs, and the cPAD includes the 3x FQPA safety factor.

a. Acute PAD

An acute RfD of 0.15 mg/kg/day was derived for females 13-50 years old based on the NOAEL of 15 mg/kg/day in the developmental toxicity study in rabbits and an uncertainty factor (UF) of 100 (10x for interspecies extrapolation and 10x for intraspecies variation). The FQPA SF was removed (equivalent to a factor of 1x) for this population. Consequently, the acute PAD (aPAD) is numerically equivalent to the acute RfD at 0.15 mg/kg/day for this population subgroup.

b. Chronic (Non-Cancer) PAD

A chronic (non-cancer) RfD of 0.016 mg/kg/day was derived based on a NOAEL of 4.8 mg/kg/day in the carcinogenicity study in rats with an uncertainty factor of 300 (10x for interspecies extrapolation, 10x for intraspecies variation, and 3x applied under FIFRA for lack of a chronic toxicity guideline study in dogs). The FQPA safety factor of 3x applies to the chronic dietary assessment. Consequently, the chronic PAD (cPAD) is 0.005 mg/kg/day.

c. Chronic (Cancer) Unit Risk

A linear low-dose approach (Q_1*) was used to characterize human health risk. The unit risk, or Q_1*, based on the occurrence of thyroid follicular cell combined adenomas/carcinomas in male rats, is 3.33 x 10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

5. Exposure Assumptions

The dietary (food) exposure analysis used for etridiazole is based on the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis used the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII). No Pesticide Data Program (PDP) or Food and Drug Administration (FDA) monitoring data were available and crop field trial data were not required for crops on which etridiazole is used as a seed treatment. Field trial data were available only for cottonseed at a 6x application rate (in-furrow at-planting treatment). Residues of etridiazole detected were less than the limit of quantitation (LOQ), which is where the tolerance is set. Based on available metabolism data, there is no reasonable expectation of finite regulable residues [etridiazole parent compound and the monoacid metabolite (3-Carb-T)] in meat, poultry, poultry and meat by-products, fat, milk and eggs. Therefore, animal commodities are not included in the dietary risk assessment. The risk assessment may be modified upon establishment of a tolerance to support use on imported tomatoes. This assessment currently uses conservative assumptions for imported tomatoes; therefore, dietary risk estimates are not likely to increase.

6. Dietary (Food) Risk Assessment

a. Acute Dietary Risk

Acute dietary risk was calculated considering what is eaten in one day and tolerance level residue values in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's level of concern.

Tolerance level residues and 100% crop treated were assumed for all commodities. Etridiazole is not registered for use on domestically grown tomatoes, but it is used on imported tomatoes. A conservative value of 100% crop treated was used for all tomato commodities (assumes all tomatoes consumed are treated with etridiazole). The established tolerance for domestic tomatoes (0.15 ppm) was used for the residue level for tomato commodities.

A Tier 1 deterministic approach was used to estimate acute dietary risk. When using a deterministic approach, the percentile of concern is the 95th, although results for the 99th and 99.9th percentiles were also calculated. The results of the analysis are shown in Table 3. At the 95th percentile of exposure, risk estimates for females 13-50 years old, the only subgroup of concern, are 1% of the aPAD and thus are not of concern. For more information on acute dietary risk assessment, see the Dietary Exposure and Risk Analysis section of the June 6, 2000 *Human Health Risk Assessment*.

Table 3. Acute Dietary Risk (Food Only)

Subgroups	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure (mg/kg)	% aPAD	Exposure (mg/kg)	% aPAD	Exposure (mg/kg)	% aPAD
Females (13-50 years)	0.001541	1.0	0.002795	1.9	0.005323	3.6

b. Chronic (Non-Cancer) Dietary Risk

A Tier 1 assessment was used to estimate chronic (non-cancer) dietary risk. Chronic (non-cancer) dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's level of concern.

As with the acute dietary assessment, tolerance level residues and 100% crop treated were assumed for all commodities. A conservative value of 100% crop treated was used for all tomato commodities (assumes all tomatoes consumed are treated with etridiazole). The established tolerance for domestic tomatoes (0.15 ppm) was used for the residue level for tomato commodities.

The risk estimate for the mostly highly exposed subgroup, children 1-6, is 31% of the cPAD and thus is not of concern. The results of the analysis, based on the uses supported through reregistration, are summarized in Table 4.

Table 4. Chronic Non-Cancer Risk (Food Only)

Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000688	14 %
Non-nursing infants	0.001024	20 %
Children (1-6 years)	0.001534	31 %

Subgroup	Exposure (mg/kg/day)	% cPAD
Females 13-19 years (not pregnant/not nursing)	0.000676	14 %
Females 13-50 years	0.000538	11 %
Males 13-19 years	0.000767	15 %

For more information on chronic dietary risk assessment, see the Dietary Exposure and Risk Analysis section of the June 6, 2000 *Human Health Risk Assessment*.

c. Chronic (Cancer) Dietary Risk

A Tier 3 assessment was used to calculate chronic (cancer) dietary risk. Exposure assumptions included residue levels of one-half the combined limits of quantitation for etridiazole and its monoacid metabolite (3-Carb-T) for all commodities except tomatoes, tolerance level residues for tomatoes (0.15 ppm), weighted average percent crop treated for all commodities except tomatoes, and 1% crop treated for imported tomatoes.. The chronic exposure value is combined with the Q_1* to determine the lifetime (cancer) risk estimate. The results of the dietary cancer risk assessment are shown in Table 5.

Table 5. Cancer Dietary Risk (Food Only)

Subgroup	Exposure (mg/kg/day)	Lifetime Risk Estimate[1]
U.S. Population	0.000005	1.6×10^{-7}

[1]Lifetime Risk Estimate = 70-year Lifetime Exposure (mg/kg/day) x Q_1*
= (0.000005 mg/kg/day) x 3.33×10^{-2} $(mg/kg/day)^{-1}$

The Agency generally considers $1x10^{-6}$ (1 in 1 million) or less to be negligible risk for cancer dietary exposure. The results of this analysis indicate that the cancer dietary (food) risk associated with the uses supported through reregistration is 1.6×10^{-7}, and thus is not of concern. For more information on chronic (cancer) dietary risk assessment, see the Dietary Exposure and Risk Analysis section of the June 6, 2000 *Human Health Risk Assessment*.

7. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or

actual monitoring data, if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether or not modeled or monitored concentrations exceed this level. Estimated environmental concentrations (EECs) that are above the corresponding DWLOC exceed the Agency's level of concern. Modeling is generally considered to be an unrefined assessment and provides high-end estimates.

Monitoring data are not available for etridiazole to enable a quantitative exposure analysis and risk assessment, so estimates were developed using models. These models estimate levels of etridiazole only, and not its degradates. The results of the acute and chronic drinking water assessments, EECs and DWLOCs are summarized in Table 6. Shaded areas denote estimated concentrations that exceed the DWLOCs.

a. Surface Water

Two scenarios were used to estimate environmental concentrations for surface water. The turf scenario reflects the golf course use and is the worst case scenario. Therefore, an estimate of the chronic surface water EECs was also done for the cotton in-furrow use since the application rate is lower and a more refined model is available. All EEC values reflect only etridiazole *per se* and do not include the degradate of dietary significance, 3-Carb-T. Available environmental fate data indicate that approximately 7% of etridiazole may degrade to form 3-Carb-T. Given the low volume of etridiazole used on golf course turf and the relative stability of the parent compound to abiotic degradation, the metabolite is not expected to contribute significantly to drinking water risk.

For surface water, GENEEC was used to estimate peak (acute) and 56-day concentrations resulting from the use on golf course tees, greens and fairways. In the past, EPA used a Tier 2 PRZM-EXAMS screening model to estimate the upper-bound concentrations in surface water for turf as well as agricultural uses. This model, in general, is based on more refined, less conservative assumptions than the Tier 1 GENEEC screening model, and provides estimates for 36-year mean concentrations. However, the Agency has determined that the Tier 2 PRZM-EXAMS model does not have the appropriate parameters to accurately model turf runoff; therefore, only GENEEC was used to model turf use for this assessment. Chronic EECs derived from GENEEC for turf use were, however, refined with the incorporation of a percent crop area (PCA) factor. It was assumed that 87% of the watershed is in golf course use, and that 19.5% of the golf course is actually treated (assuming tees, greens and fairways average about 35 acres out of a 180-acre golf course, or 19.5%). The resulting PCA factor is 17%.

Peak EECs in surface water (230 ppb) based on two applications at 3.8 lbs ai/A at 10-day intervals to golf course turf result in acute risks that are below the drinking water levels of comparison (DWLOCs)

of 4300 ppb for females 13-50 years of age, the population subgroup of concern. Thus, acute risks from surface water are not of concern.

Potential 56-day average concentrations of etridiazole in surface water after application to turf (32.3 ppb) result in chronic non-cancer risk that is not of concern for any population subgroup. For cotton use, potential chronic (36-year average) concentrations of etridiazole in surface water are 0.05 ppb, which is below the non-cancer and cancer DWLOCs for all population subgroups, and thus are not of concern.

Potential concentrations of etridiazole in surface water for turf use (32.3 ppb), assuming treatment of tees, greens and fairways, are above the cancer DWLOC of 1 ppb for the general U.S. population. Thus, chronic cancer risk from surface water after application to golf course turf is of concern.

b. Ground Water

Ground water concentrations of etridiazole were estimated using the SCI-GROW (Tier I) computer model. Model simulations indicate that the maximum total etridiazole residue concentration after two applications at 3.8 lbs ai/A at 10-day intervals is not likely to exceed 0.93 ppb. This is below the DWLOCs for all population subgroups for acute, chronic and cancer risks, and thus is not of concern.

The results of both surface and ground water model estimates and their comparison with the DWLOCs are summarized in Table 6. For more information on drinking water risks and the calculations of the DWLOCs, see the Water Exposure section of the June 6, 2000 *Human Health Risk Assessment*, the Water Resource section of the *Environmental Fate and Effects Division Risk Assessment for the Reregistration Eligibility Decision on 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole (Etridiazole), May 22, 2000* and *Terrazole: Refined Tier I Chronic Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment, May 26, 2000*.

Table 6. Drinking Water DWLOC and EEC Comparisons

Population Subgroup	DWLOCs (ppb)			EECs (ppb)			
		Chronic		Ground Water[1]	Surface Water		
	Acute	Non-Cancer	Cancer	Acute & Chronic	Acute[2]	Chronic Cancer & Non-Cancer	
						Tier 1[3] (Turf)	Tier 2[4] (Cotton)
Females (13-50 years)	4300	130	1	0.93	230	32.3	0.05
Non-nursing infants (<1 year)	NC[5]	40					
Children (1-6 years)	NC	35					
Females (13-19 years) not pregnant, not nursing	NC	130					
Males (13-19 years)	NC	150					
U.S. population	NC	150					

[1]Based on SCIGROW model, Tier 1, using typical application rate (two applications at 3.8 lb ai/A at 10-day intervals) to golf course tees, greens and fairways.

[2]Based on GENEEC model, Tier 1, using typical application rate (two applications at 3.8 lb ai/A at 10-day intervals) to golf course tees, greens and fairways, peak concentration.

[3]Based on GENEEC model, Tier 1, using typical application rate (two applications at 3.8 lb ai/A at 10-day intervals to golf course fairways and five applications at the same rate to tees and greens), 56-day average concentration.

[4]Based on PRZM/EXAMS model, Tier 2, using typical application rate for in-furrow application of 0.38 lb ai/A, 36-year mean, on cotton.

[5]Not calculated. Acute DWLOC was calculated only for females 13-50 because this was the only group for which acute dietary exposure was assessed.

8. Residential and Other Non-Occupational Risk

There are no registered homeowner uses of etridiazole, so a residential risk assessment was not conducted. The only non-occupational exposure expected to occur is short-term exposure on treated golf courses.

a. Short-Term Non-Occupational Non-Cancer Risk

The short-term toxicological endpoint for etridiazole is *in utero* effects observed in a developmental study in rabbits at the LOAEL of 45 mg/kg/day. This is the same study and endpoint used in the acute dietary assessment and is applicable only to females of childbearing age. A risk assessment was

conducted for female golfers using the developmental NOAEL of 15 mg/kg/day. The FQPA SF is not applicable to this endpoint for the reasons discussed in Section III.A.1.b. For this assessment, the default dermal absorption factor of 100% was used. Because an appropriate short-term endpoint was not available for the general population, including infants and children, a risk assessment for this exposure scenario was not conducted for the general population. Inhalation exposures are not expected for golfers, and so were not calculated for golf course scenarios.

An acceptable chemical-specific study of transferrable turf residues was used to estimate the risk presented by postapplication entry onto a golf course. A golfer was assumed to be exposed for four hours per day, 18 days over the course of one year, 12 hours after application of etridiazole. For the population subgroup assessed, females 13-50 years of age, a margin of exposure (MOE) of 100 or greater is not of concern. The MOE was estimated at 17,000, which is not of concern.

b. Non-Occupational Cancer Risk

Cancer risk estimates were determined for all adult golfers using the same100% dermal absorption factor, residue data and exposure parameters as for the non-occupational non-cancer risk assessment. The estimated cancer risk for adult golfers is 8.9×10^{-7}, which is a level the Agency considers to be negligible for excess lifetime cancer risk.

9. Aggregate Risk

Aggregate risk includes the combined risk from dietary exposure through both food and drinking water, as well as from exposures to residential and other non-occupational sources (in this case, exposure to treated golf courses).

a. Acute Aggregate Risk

The acute aggregate risk assessment considers a one-day oral exposure from food and water only. Females 13-50 years old were the only population subgroup for which acute assessments were done. Estimated risks for etridiazole from food and water indicate that 1% of the aPAD at the 95th percentile is occupied by dietary (food) exposure, and that surface and ground water EECs (230 ppb and 0.93 ppb, respectively) are below the DWLOC for this population subgroup (4300 ppb). Thus, acute aggregate risk from food and water is not of concern.

b. Short-Term Aggregate Risk

In order to determine the short-term aggregate risk, the Agency combines the short-term risks from any non-occupational exposures with the risks from food and drinking water. In the case of etridiazole, the only non-occupational exposures are by golfers on treated golf courses. The only short-term toxicity endpoint identified for etridiazole was for females 13 to 50 years of age; consequently, the short-term aggregate risk is calculated only for this subpopulations. Since the Agency does not have any reliable monitoring data from which to estimate the exposures in water, it had to rely on the DWLOC method to determine if the risk cup is exceeded. The short-term risk for golfers (expressed as a margin of exposure) was estimated to be 17,000. The short-term dietary risk for food for the subpopulations of concern was estimated to be 0.4%, equivalent to an MOE of 28,000. (The Agency assumes that the chronic exposure from etridiazole residues in food is equal to the short-term exposure.) By adding the exposures associated with these risks, comparing them to the short-term toxicological endpoint (i.e., a NOAEL of 15 mg/kg/day), and determining the amount of room left in the risk cup, one can determine the level of residues in drinking water that would be allowed, assuming that a person consumes 2 liters of water per day (the DWLOC), before the cup is full. In this instance, it was determined that drinking water could contain up to 4300 ppb before there is a risk of concern (i.e., a margin of exposure of less than 100). The Agency did not model for short-term exposures from drinking water but instead used the model estimate for surface water acute exposures for comparison to the DWLOC. This is a conservative estimate since the level of residues in drinking water to which a person could be exposed over a short-term period would be expected to be less than the maximum (or acute) level to which one could be exposed. The short-term DWLOC was estimated to be 4300 ppb, while the estimated acute exposure was modeled to be 230 ppb.

c. Chronic (Non-Cancer) Aggregate

Chronic non-cancer aggregate risk includes exposure from food, water and non-occupational sources, which in this case includes only exposure to treated golf courses. There are no chronic non-occupational exposures, so chronic non-cancer aggregate risk estimates include only chronic dietary (food and water) exposures. Estimated risks from food for the most highly exposed subgroup, children 1-6, indicate that 31% of the cPAD is occupied by dietary (food) exposure, and that chronic surface and ground water EECs (32.3 ppb and 0.93 ppb, respectively) are below the DWLOC for this population subgroup (35 ppb). Therefore, chronic non-cancer aggregate risks are not of concern.

d. Chronic (Cancer) Aggregate

Cancer aggregate risk estimates include chronic dietary (food and water) and non-occupational (in this case, golf course) exposures. The estimated cancer risk for adult golfers is 8.9×10^{-7}, and the estimated cancer risk from food only is 1.6×10^{-7}. The combined cancer risk estimate for food and golf

course exposures is $1.1x10^{-6,}$ which is not of concern. However, the Tier 1 chronic surface water EEC reflecting use on turf (32.3 ppb) exceeds the cancer DWLOC for the general U.S. population (1 ppb). Therefore, cancer aggregate risk estimates for the general population are of concern due to chronic surface water EECs associated with turf use.

10. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of etridiazole include individual (or private) users and professional (or commercial) applicators who mix, load, and/or apply pesticides. Dermal and inhalation risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from an animal study. For etridiazole, short- and intermediate-term MOEs greater than 100 and long-term MOEs greater than 300 are not of concern. The Agency also conducted an assessment of the cancer risk associated with etridiazole following exposures to occupational handlers. Cancer risks to workers of $1x10^{-6}$ (1 in 1 million) and less are considered to be negligible. For more information on the assumptions and calculations of potential risks to workers, see the *Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, June 5, 2000 and the Occupational Exposure section of the June 6, 2000 *Human Health Risk Assessment*.

a. Occupational Toxicity

The acute toxicity profile for etridiazole is summarized below in Table 7.

Table 7. Acute Toxicity Profile for Etridiazole[1]

Guideline	MRID	Study	Results	Toxicity Category
870.1100 (§81-1)	43724501	Acute Oral - Rat	LD_{50} (males) = 1141 mg/kg LD_{50} (females) = 945 mg/kg LD_{50} (males and females combined) = 1028 mg/kg	III
870.1200 (§81-2)	43724502	Acute Dermal - Rabbit	LD_{50} (males and females combined) > 5000 mg/kg	IV
870.1300 (§81-3)	43724503	Acute Inhalation - Rat	LC_{50} (males and females combined) > 5.7 mg/L	IV
870.2400 (§81-4)	43724504	Primary Eye Irritation - Rabbit	Moderate Eye Irritant	III
870.2500 (§81-5)	43724505	Primary Dermal Irritation - Rabbit	Non Irritant	IV
870.2600 (§81-6)	43724506	Dermal Sensitization - Guinea Pig- unspecified purity of Terrazole technical	Moderate Dermal Sensitizer	N/A

[1]The percent active ingredient of the technical test material used in each of the acute toxicity studies was reported as 98.6% a.i., unless specified otherwise.

The Agency anticipates that, with one exception, only short- and intermediate-term occupational exposures to etridiazole will occur, given its seasonal use pattern. The exception is postapplication handling of treated potting soil by nursery and greenhouse workers, where exposure could occur on a long-term basis.

No acceptable dermal penetration study is available in the etridiazole toxicity database. In addition, the dermal toxicity studies submitted to the Agency were determined to be inadequate for regulatory purposes. Therefore, the default value of 100% dermal absorption was used in this risk assessment. However, the acidic pH of etridiazole technical (pH 3-4 in water) would cause considerable skin irritation and would most likely breach the skin barrier. Therefore, 100% dermal absorption is possible. Oral studies were used for all of the inhalation endpoints. Therefore, the default value of 100% inhalation absorption was used.

1) Short-Term Dermal and Inhalation Endpoints

The short-term endpoint for calculating dermal and inhalation risk was reduced fetal body weights, decreased viability and increased skeletal malformations/variations observed in an oral developmental toxicity study in rabbits at a LOAEL of 45 mg/kg/day. A NOAEL of 15 mg/kg/day was selected.

2) Intermediate- and Long-Term Dermal and Inhalation Endpoints

The intermediate- and long-term endpoint (dermal and inhalation) was increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis in male rats observed at the LOAEL of 30.4 mg/kg/day in a carcinogenicity study. The NOAEL was 4.8 mg/kg/day. A 3x FIFRA uncertainty factor was applied to the long-term endpoints due to the lack of an acceptable guideline chronic toxicity study.

3) Cancer Endpoint

Etridiazole is classified as a Group B2 Probable Human Carcinogen based on multiple tumor types in male and female rats. A linear low-dose (Q_1*) approach was used to characterize human health risk. The unit risk, Q_1*, is 3.33×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

An overview of the toxicity endpoints used for the occupational risk assessment is outlined in Table 8. For more occupational toxicity information used to assess risks to workers, see the Hazard Profile section of the June 6, 2000 *Human Health Risk Assessment* and the *Revised Toxicology Chapter of the Reregistration Eligibility Decision,* September 13, 2000.

Table 8. Summary of Etridiazole Occupational Toxicity Endpoints

Exposure Scenario	Dose (mg/kg/day)	Absorption Factor*	Endpoint	Study
Short-Term (Dermal and Inhalation) Target MOE 100	Oral NOAEL=15	100%	Reduced fetal body weights, decreased viability and increased skeletal malformations/variations at the LOAEL of 45 mg/kg/day	Developmental-Rabbit (00104999)
Intermediate-Term (Dermal and Inhalation) Target MOE 100	Oral NOAEL=4.8	100%	Decreased body weight, increased liver weight (absolute and relative), renal tubule cell karyomegaly, hepatocytomegaly, spongiosis hepatis, cholangiectasis, centrilobular pigmentation; liver, testicular and thyroid tumors at the LOAEL of 30.4 mg/kg/day	Oncogenicity - Rat (40747901)
Long-Term (Dermal and Inhalation) Target MOE 300**				

Exposure Scenario	Dose (mg/kg/day)	Absorption Factor*	Endpoint	Study
Chronic (Cancer)	**Group B2 - "Probable human carcinogen" - Q_1* = 3.33 x 10^{-2} (mg/kg/day)$^{-1}$** in human equivalents [converted from animals to humans by use of the (mg/kg body weight)$^{3/4}$ cross species scaling factor].			

*Oral NOAELs were selected. Dermal and inhalation absorption factors of 100% (default values) were used for route-to-route extrapolation.

**MOE includes the conventional 100x uncertainty factor (10x for interspecies variability, 10x for interspecies extrapolation) and 3x for lack of a chronic oral toxicity study in dogs.

b. Occupational Exposure

Chemical-specific handler exposure data were not available for etridiazole, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values used by the Agency, and the PHED unit exposure values are the best available estimates of exposure.

Anticipated use patterns, application methods, and range of application rates were derived from current labeling. The daily amount treated is based in part on standard assumptions and in part on information provided by the technical registrant. Etridiazole can be applied by groundboom, chemigation, handwand, broadcast spreader, tractor-drawn spreader or hand dispersal.

In-furrow crop treatment rates (soil-incorporated) for etridiazole range from 0.13 to 0.38 lbs. ai per acre. Soil is also treated for ornamental plants for nurseries and greenhouses. The typical rate for soil drench treatment is 6 oz ai/1000 sq. ft. (0.375 lb/1000 sq. ft. or 16.3 lb/acre), with a range of 1.5 oz ai/1000 sq. ft. (4.1 lb) to 17.5 oz ai/1000 sq. ft. (1.09 lb ai/1000 sq. ft. or 47.6 lb ai/acre). Etridiazole can also be added dry to potting soil, typically at 1.1 oz ai/cubic yard. Application to turf on golf courses is in the range of 0.7 to 2.8 oz ai/1000 sq. ft. (1.9 lb ai/acre to 7.6 lb ai/acre). Seed treatment rates range from 0.0078 lb ai/100 lbs seed to 0.0625 lb ai/100 lb seed.

Occupational handler exposure assessments are conducted using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach (going from minimal to maximum levels of protection) to obtain an appropriate MOE. The lowest tier is represented by the baseline exposure scenario (i.e., single layer clothing, socks, and shoes), followed by, if MOEs are still of concern, increasing levels of

risk mitigation [i.e., personal protective equipment (PPE) and engineering controls (EC)]. End use product labels currently specify a wide range of personal protective equipment.

Based on the handler activity pattern, the duration of exposure is expected to be only short-term (1-7 days) and intermediate-term (1 week to 6 months) for occupational handlers. The use pattern for turf products results in the greatest amount of exposure with a maximum of up to 10 applications per season for golf courses. Therefore, long-term (chronic) exposure is not anticipated nor expected, and a long-term (chronic) exposure risk assessment for handlers is not required.

c. Handler Risks

There are potential occupational exposures to pesticide handlers using etridiazole. Occupational handlers are potentially exposed via dermal and inhalation routes. Worker risk is measured by a Margin of Exposure (MOE) which determines how close occupational exposure comes to the NOAEL taken from animal studies. Short- and intermediate-term MOEs that are greater than 100 are not of concern. Based on the current use patterns, 24 occupational exposure scenarios were identified for etridiazole which are presented as a total of 55 assessments to account for variable application rates.

EPA conducted an assessment of the cancer risk associated with etridiazole following exposures to occupational handlers. For the cancer assessment, two scenarios were used. "Private" represents typical exposures (e.g., typical application rates) experienced by growers who apply etridiazole to their own fields, greenhouse, golf course, etc., while "commercial" represents typical exposures experienced by commercial handlers. Because greenhouses, nurseries, and golf courses usually have their own certified pesticide applicators, and because private and commercial farm sizes vary widely, multipliers ranging from 3x to 10x were applied to the number of expected exposures by private handlers in order to obtain the number of exposures expected for commercial handlers.

Risks for occupational handlers of etridiazole are of concern for some scenarios. In some cases, the calculated risks can be mitigated with additional protective measures such as engineering controls. However, for some scenarios, engineering controls are not feasible. The Agency has risk concerns for occupational handlers loading/applying liquids and dusts for commercial seed treatment, loading/applying granules by belly grinder, power dust blower and push-type spreader, mixing/loading/applying wettable powders, and dispersing granules by hand. These scenarios and corresponding risk estimates are shown in Table 9. Footnotes accompanying the risk estimates denote the level of PPE needed to achieve the MOE or cancer risk estimate shown. In many cases, this level of PPE exceeds that specified on current product labels. Current product labels vary widely in the levels of PPE specified, from long-sleeved shirt and pants, shoes and socks to double-layer clothing, chemical-resistant gloves, footwear, eyewear and respiratory protection.

The levels of protection that formed the basis for calculations of exposure in this assessment are as follows:

Baseline:	Long-sleeved shirt and long pants, shoes and socks
Minimum PPE:	Baseline and chemical resistant gloves
Maximum PPE:	Baseline, chemical resistant gloves, coveralls and an organic vapor respirator
Engineering controls:	Engineering controls such as a package-based system (e.g., water-soluble packaging for wettable powders) or other closed systems. Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures).

These risk estimates suggest that occupational handler risks are largely due to estimated dermal exposures; the combined dermal and inhalation MOEs were not significantly different from the dermal MOEs. However, these MOEs are likely to underestimate inhalation exposures. The vapor pressure of etridiazole is higher than the mean vapor pressure of chemicals in PHED, so actual inhalation risks are expected to be higher than indicated by the calculated inhalation MOEs. In addition, a chemical-specific postapplication exposure study in workers handling treated potting soil showed that 70% of the total dose was due to inhalation. To address the uncertainties associated with inhalation risks, the Agency is requiring inhalation toxicity and exposure data.

As indicated previously, seven states hold Special Local Need [Section 24(c)] registrations of Terrazole 35% Wettable Powder for use on tobacco. These registrations were granted between March and June, 2000. Risks associated with this use site have not been explicitly considered in this risk assessment and reregistration eligibility decision. However, based on label application rates and directions for use on the 24(c) labels, the Agency believes that occupational risks are within the range of those contained in this risk assessment, and are addressed by mitigation agreed to by the registrant.

Handler risk estimates are summarized in Table 9 below. The mitigation measures needed to bring risk estimates to a level that are not of concern are also indicated.

1) Seed Treatment

Mixing/loading

Mixing/loading **emulsifiable concentrate** (EC) and **flowable concentrate** (FC) for on-farm treatment at all application rates results in MOEs greater than 100 when single-layer clothing is used. However, single-layer clothing and chemical-resistant gloves were needed to bring cancer risks to a level that is not of concern. See Table 9, Scenario 3b.

Mixing/loading/applying

Loading/applying **EC and FC** for commercial seed treatment at the typical application rate with single-layer clothing and chemical-resistant gloves results in cancer risks between 10^{-4} and 10^{-5}. At the high application rate, with single-layer clothing and chemical-resistant gloves, the intermediate-term MOE is 42. The effects of adding PPE could not be quantitatively assessed because suitable data were not available. See Table 9, Scenario 3c.

Handling and bagging for commercial seed treatment with **EC and FC** results in MOEs greater than 100 when single-layer clothing is used. However, chemical-resistant gloves were needed to bring cancer risks to a level that is not of concern. See Table 9, Scenario 3d.

Loading **dust** for commercial seed treatment at the typical application rate, with engineering controls, results in a cancer risk estimate of 10^{-5}. See Table 9, Scenario 4.

Mixing/loading/applying **dust** for on-farm seed treatment with single-layer clothing and chemical-resistant gloves results in an intermediate-term MOE of 45 and cancer risk for commercial applicators of 10^{-4}. The effects of adding PPE could not be quantitatively assessed because suitable data were not available. See Table 9, Scenario 8.

2) Golf Course Use

Mixer/loaders, applicators, mixer/loader/applicators

Mixing/loading **wettable powder** for groundboom application to 40 acres (golf course tees, greens and fairways) results in MOEs ranging from 7 to 87 and cancer risks between 10^{-4} and 10^{-5} with coveralls, chemical-resistant gloves, and OV respirator. See Table 9, Scenarios 1a, 5a, and 14. Use of engineering controls results in MOEs of 100 or greater but cancer risks remain of concern.

These scenarios, 1a, 5a and 14, were also assessed assuming application to tees and greens only, thus reducing the acres treated to 5 acres. MOEs range from 56 to 6400 with maximum PPE; cancer risks are between 10^{-5} and 10^{-8}.

Mixing/loading **wettable powder** for chemigation for use on turf results in MOEs greater than 100 when single-layer clothing and chemical-resistant gloves are used. However, single-layer clothing, chemical-resistant gloves, coveralls and an OV respirator were needed to bring cancer risks to a level that is not of concern. See Table 9, Scenario 1b.

Loading/applying **granules** to turf with a belly grinder at the typical application rate using maximum PPE results in margins of exposure of 35 (short-term) and 13 (intermediate-term) and cancer risks

between 10^{-4} and 10^{-6}. Loading/applying granules to turf with a push-type spreader at the typical application rate using maximum PPE results in margins of exposure of 53 (short-term) and 20 (intermediate-term) and cancer risks between 10^{-4} and 10^{-5}. See Table 9, Scenarios 11 and 12.

Loading/applying **granules** to turf using a tractor-pulled spreader with single-layer clothing results in MOEs greater than 100 and cancer risks that are not of concern. See Table 9, Scenario 13.

3) Nursery Use

Mixing/loading/applying

Mixing/loading/applying **granules** in-furrow to nursery soil with single-layer clothing results in MOEs and cancer risks that are not of concern. See Table 9, Scenario 6.

Mixing/loading/applying **EC** in-furrow to nursery soil with single-layer clothing results in intermediate-term MOEs of less than 100 and cancer risks that are of concern. With the additional of chemical-resistant gloves, MOEs and cancer risks are not of concern. See Table 9, Scenario 7.

Mixing/loading/applying **EC** as a drench with a low-pressure handwand using single-layer clothing results in intermediate-term MOEs less than 100 and cancer risks less than 10^{-6}. With the addition of chemical-resistant gloves, MOEs and cancer risks are not of concern. See Table 9, Scenario 9.

Mixing/loading/applying **EC** as a drench with a high-pressure handwand using coveralls over single-layer clothing, chemical-resistant gloves and an OV respirator results in commercial cancer risks of 10^{-5}. See Table 9, Scenario 10.

Loading/applying **granules** with a belly grinder, power dust blower and push-type spreader with coveralls over single-layer clothing, chemical-resistant gloves and an OV respirator results in margins of exposure ranging from 4 to 15 and cancer risks of 10^{-4}. See Table 9, Scenarios 17-20.

Loading/applying **granules** (3% ai formulation) with a tractor-drawn spreader at the maximum application rate with single-layer clothing results in MOEs greater than 100 and cancer risks of that are not of concern. See Table 9, Scenario 21.

Loading/applying **granules** (5% ai formulation) with a tractor-drawn spreader at the maximum application rate with single-layer clothing results in cancer risks of 10^{-5}. With the addition of chemical-resistant gloves, cancer risks are 10^{-6}. See Table 9, Scenario 22.

Loading/applying **granules** with a power dust blower could not be quantitatively assessed because no data are available for assessing this scenario. See Table 9, Scenario 23.

Applying **granules** by hand with maximum PPE results in margins of exposure of 13 (short-term) and 4.9 (intermediate-term) and cancer risks of 10^{-5}. See Table 9, Scenario 24.

4) Greenhouse/Potting Soil Use

Mixing/loading/applying

Mixing/loading/applying **granules** to potting soil with single-layer clothing results in MOEs and cancer risks that are not of concern. See Table 9, Scenario 15.

Mixing/loading/applying **wettable powder** to potting soil with single-layer clothing results in MOEs that are not of concern, but cancer risks greater than 10^{-6}. With the addition of chemical-resistant gloves, cancer risks are not of concern. See Table 9, Scenario 16.

4) Cotton Use

Mixing/loading

Loading **granules** for in-furrow application to cotton with single-layer clothing results in MOEs greater than 100 and cancer risks that are not of concern. See Table 9, Scenario 2.

Mixing/loading **EC** for in-furrow application to cotton with single-layer clothing results in MOEs and cancer risks less than 100. With the addition of chemical-resistant gloves, MOEs and cancer risks are not of concern. See Table 9, Scenario 3a.

Mixing/loading/applying

Applying **EC** for in-furrow application to cotton with single-layer clothing results in MOEs greater than 100 and cancer risks that are not of concern. See Table 9, Scenario 5b.

Table 9. Summary of Risk Estimates for Etridiazole Handlers

Exposure Scenario	Crop Type or Target Acres Treated or Gal./ Application	Application Rate	Combined MOEs[1] (dermal and inhalation)		Lifetime Cancer	
			ST[2] Target 100	IT[3] Target 100	Private	Commercial
Occupational Mixer/Loader						
(1a) mixing/loading wettable powder for groundboom application	turf/ golf course 40 acres (tees, greens, fairways)	low	87[6]	32[6]	NE[10]	NE[10]
			1200[7]	440[7]		
		typical	43[6]	16[6]	6.8×10^{-5} [6]	2.0×10^{-4} [6]
			590[7]	220[7]	5.0×10^{-6} [7]	1.5×10^{-5} [7]
		high	22[6]	8[6]	NE[10]	NE[10]
			290[7]	110[7]		
(1b) mixing/loading wettable powder for chemigation	turf/ golf course 2 acres	low	310[4]	120[4]	NE[10]	NE[10]
		typical	160[4]	1100[5]	4.0×10^{-7} [6]	4.0×10^{-6} [6]
		high	110[4]	720[5]	NE[10]	NE[10]
(2) loading granular for in-furrow application	cotton 80 acres	Uniroyal estimate	1900[4]	720[4]	3.0×10^{-7} [4]	1.5×10^{-6} [4]
		typical	4600[4]	1700[4]	3.8×10^{-7} [4]	1.5×10^{-6} [4]
		high	2900[4]	1100[4]	NE[10]	NE[10]
(3a) mixing/loading EC/FC for in-furrow application	cotton 80 acres	Uniroyal estimate	1300[5]	480[5]	4.5×10^{-7} [5]	2.3×10^{-6} [5]
		typical	2400[5]	910[5]	7.2×10^{-7} [5]	2.9×10^{-6} [5]
		high	1200[5]	460[5]	NE[10]	NE[10]
(3b) mixing/loading EC/FC for on-farm seed treatment	peanuts 80 acres	low	550[4]	210[4]	NE[10]	NE[10]
		typical	280[4]	100[4]	1.2×10^{-7} [5]	3.5×10^{-7} [5]
	cotton 80 acres	high	350[4]	130[4]	NE[10]	NE[10]
(3c) loading/applying EC/FC for commercial seed treatment (Uniroyal study)	seed 330K lbs	Uniroyal estimate[11]	270[5]	100[5]	4.3×10^{-5} [5,8]	1.3×10^{-4} [5,8]
		high	110[5]	42 [5,8]	NE[10]	NE[10]

Exposure Scenario	Crop Type or Target Acres Treated or Gal./ Application	Application Rate	Combined MOEs[1] (dermal and inhalation)		Lifetime Cancer	
			ST[2] Target 100	IT[3] Target 100	Private	Commercial
(3d) seed handler/bagger: EC/FC for commercial seed treatment (Uniroyal study)	seed 330K lbs	Uniroyal estimate[11]	1200[4]	430[4]	$1.6x10^{-6}$ [5,8]	$4.8x10^{-6}$ [5,8]
		high	480[4]	180[4]	NE[10]	NE[10]
(4) loading dust for commercial seed treatment	seed 330K lbs	low	200[5]	120[6]	NE[10]	NE[10]
		typical	100[5]	60[6]	$7.3x10^{-5}$ [6]	$2.2x10^{-4}$ [6]
				800[7]	$5.4x10^{-6}$ [7]	$1.6x10^{-5}$ [7]
		high	40[6]	15[6]	NE[10]	NE[10]
			540[7]	200[7]		
Occupational Applicator						
(5a) applying WP with groundboom sprayer	turf/ golf course 40 acres (tees, greens, fairways)	low	800[4]	240[4]	NE[10]	NE[10]
		typical	400[4]	150[4]	$5.5x10^{-6}$ [6]	$1.6x10^{-5}$ [6]
					$2.5x10^{-6}$ [7]	$7.6x10^{-6}$ [7]
		high	200[4]	100[6]	NE[10]	NE[10]
(5b) applying EC/FC in-furrow	cotton 80 acres	Uniroyal estimate	2100[4]	770[4]	$2.8x10^{-7}$ [4]	$2.0x10^{-6}$ [4]
		typical	4000[4]	1500[4]	$4.4x10^{-7}$ [4]	$1.8x10^{-6}$ [4]
		high	2000[4]	750[4]	NE[10]	NE[10]
(6) mixing/loading/ applying granules in-furrow	soil 80 acres	Uniroyal estimate	920[4]	340[4]	$6.4x10^{-7}$ [4]	$3.2x10^{-6}$ [4]
		typical	1800[4]	660[4]	$9.9x10^{-7}$ [4]	$4.0x10^{-6}$ [4]
		high	1400[4]	520[4]	NE[10]	NE[10]
Occupational Mixer/Loader/Applicator Estimates						
(7) mixing/loading/ applying EC/FC in-furrow	soil 80 acres	low	120[4]	720[5]	NE[10]	NE[10]
		typical	160[4]	960[5]	$6.8x10^{-7}$ [5]	$2.7x10^{-6}$ [5]

Exposure Scenario	Crop Type or Target Acres Treated or Gal./ Application	Application Rate	Combined MOEs[1] (dermal and inhalation)		Lifetime Cancer	
			ST[2] Target 100	IT[3] Target 100	Private	Commercial
		high	1300[5]	480[5]	NE[10]	NE[10]
(8) mixing/loading/ applying (dry) in planter box	seed 1440 lbs	high	120[5]	45[5,8]	$3.4x10^{-6}$ [5,8]	$1.0x10^{-4}$ [5,8]
(9) mixing/ loading/applying EC/FC as drench using low pressure handwand	soil 5,000 s.f. - 0.5 acres	typical	140[4]	12,000[5]	$5.6x10^{-8}$ [5]	$5.6x10^{-7}$ [5]
(10) mixing/ loading/applying EC/FC as drench using high pressure handwand	soil 1000 gallons	high	320[4]	120[4]	$3.5x10^{-6}$ [6,9]	$3.5x10^{-5}$ [6,9]
(11) loading and applying granules using belly grinder	turf/ golf course 1 acre	typical	35[6,9]	13[6,9]	$1.7x10^{-5}$ [6,9]	$1.7x10^{-4}$ [6,9]
(12) loading and applying granules using push-type spreader	turf/ golf course 5 acres	typical	53[6,9]	20[6,9]	$1.1x10^{-5}$ [6,9]	$1.1x10^{-4}$ [6,9]
(13) loading and applying granules using tractor-pulled spreader	turf/ golf course 5 acres	typical	3400[4]	1300[5]	$6.8x10^{-7}$ [4]	$2.0x10^{-6}$ [4]
(14)mixing/loading/ applying WP using groundboom	turf/ golfcourse 40 acres (tees, greens and fairways)	low	64[6]	24[6]	NE[10]	NE[10]
			600[7]	230[7]		
		typical	40[6]	15[6]	$7.3x10^{-5}$ [6]	$1.5x10^{-4}$ [6]
			380[7]	140[7]	$7.8x10^{-6}$ [7]	$1.6x10^{-5}$ [7]
		high	20[6]	7[6]	NE[10]	NE[10]
			190[7]	71[7]		
(15) mixing/load-ing/applying granules	potting soil 10 cubic yards	typical	290,000[4]	110,000[4]	$6.2x10^{-9}$ [4]	$1.9x10^{-8}$ [4]

Exposure Scenario	Crop Type or Target Acres Treated or Gal./ Application	Application Rate	Combined MOEs[1] (dermal and inhalation)		Lifetime Cancer	
			ST[2] Target 100	IT[3] Target 100	Private	Commercial
(16) mixing/loading/ applying WP	potting soil 10 cubic yards	typical	370[4]	140[4]	$2.9x10^{-7}$ [5]	$8.6x10^{-7}$ [5]
(17) loading/applying granules (8G) with a belly grinder	soil 1 acre	maximum	9[6,9]	4[6,9]	$1.8x10^{-4}$ [6,9]	$5.3x10^{-4}$ [6,9]
(18) loading/applying granules (5G) with a belly grinder	soil 1 acre	maximum	14[6,9]	3[6,9]	$2.0x10^{-4}$ [6,9]	$5.9x10^{-4}$ [6,9]
(19) loading/applying granules (5G) with a push-type spreader	soil 1 acre	maximum	15[6,9]	5[6,9]	$1.3x10^{-4}$ [6,9]	$3.9x10^{-4}$ [6,9]
(20) loading/applying granules (8G) with a push-type spreader	soil 1 acre	maximum	15[6,9]	6[6,9]	$1.1x10^{-4}$ [6,9]	$3.4x10^{-4}$ [6,9]
(21)loading/applying granules (8G) with a tractor-pulled spreader	soil 5 acres	maximum	1000[4]	370[4]	$1.8x10^{-6}$ [4]	$5.3x10^{-6}$ [4]
(22) loading/applying granules (5G) with a tractor-pulled spreader	soil 5 acres	maximum	890[4]	330[4]	$2.0x10^{-6}$ [5]	$6.0x10^{-6}$ [5]
(23) loading/applying granular via power dust blower[8]	no data	no data	no data	no data	no data	no data
(24) dispersing granules by hand	soil 5000 s.f.		13[6,9]	4.9[6,9]	$2.5x10^{-5}$ [6,9]	$7.4x10^{-5}$ [6,9]

[1]Combined MOEs are dominated by dermal exposure.

[2]Short-term (≤7 days)

[3]Intermediate-term (8 days to several months)

[4]This risk estimate reflects baseline protection (single-layer clothing).

[5]This risk estimate reflects single-layer clothing plus chemical-resistant gloves.

[6]This risk estimate reflects coveralls over clothing, chemical-resistant gloves, organic-vapor-removing (OV) respirator.

[7]This risk estimate reflects the use of engineering controls, i.e. water-soluble bag or closed system.

[8]No data are available for assessing the effects of engineering controls on this scenario.

[9]Engineering controls do not or are not known to exist for this scenario.

[10]Not evaluated; cancer risks are estimated only at typical application rate.

[11]Closely approximates typical application rate.

For more information on the occupational risks, see the *Occupational Exposure and Risk Assessment* section of the June 6, 2000 Human Health Risk Assessment.

d. Occupational Postapplication Exposure and Risk

Occupational postapplication scenarios assessed for etridiazole include greenhouse or nursery workers handling treated potting soil, golf course workers engaged in turf maintenance, and farmers handling treated seed for planting. Based on the etridiazole use pattern, there is potential for short- and intermediate-term postapplication exposure to etridiazole residues for workers associated with turf, cotton, seed treatment and potting soil uses. In addition, long-term exposure could occur for postapplication greenhouse/nursery workers handling treated potting soil. MOEs of 100 or greater for short- and intermediate-term postapplication exposure and 300 or greater for long-term postapplication exposure are not of concern.

Postapplication dermal risks for golf course workers are summarized in Table 10. Only short- and intermediate-term risks were estimated; long-term exposure is not expected. These risk estimates were derived from etridiazole-specific magnitude of residue and transfer of residue studies from golf courses. These risk estimates are not of concern, as long as the current restricted entry interval (REI) of 12 hours is observed.

Table 10. Dermal Risk Estimates for Postapplication Golf Course Workers

Exposure Scenario		Residue (µg/cm ^{2})	Transfer Factor (cm^2/hr)	ST[2] MOE Target 100	IT[3] MOE Target 100	Cancer Risk
Tractor Mowing	after application	0.13	500	3500	1300	2.0 x 10^{-5}
	after 12 hours	0.05[4]	500	9000	2800	2.8 x 10^{-6}
Push-mowing	after application	0.13	1000	1700	650	4.0 x 10^{-5}
	after 12 hours	0.05[4]	1000	4500	1400	5.6 x 10^{-6}

[1]Based on Gaydosh, K., 1994. MRID No. 432878-01 and 432878-02.

[2]Short-term

[3]Intermediate-term

[4]All study data support turf transferrable residues ≤0.05 µg/cm^2 at 12 hours after application; therefore this represents an upper-bound estimate.

Postapplication risks for greenhouse and nursery workers are summarized in Table 11. Short-, intermediate- and long-term risks were estimated. These risk estimates are derived from a high quality study measuring dermal and inhalation exposures to etridiazole in a greenhouse setting. Because workers participating in the study were engaged in potting treated soil without the use of gloves at the highest label application rate for four hours, these risk estimates are expected to be conservative and protective for other soil-contact activities as well. The margins of exposure are not of concern, as long as the current restricted entry interval (REI) of 12 hours is observed. Cancer risks, however, remain greater than 1x10^{-6} even after 24 hours.

Table 11. Dermal and Inhalation Risks for Postapplication Nursery Workers[1]

Exposure Scenario		Total Residue (mg/cm^2) [2]	Transfer Factor (cm^2/hr)	ST[3] MOE Target 100	IT[4] MOE Target 100	LT[5] MOE Target 300	Cancer Risk
Potting/ handling treated soil	after 12 hours	0.375	NA[6]	2400	900	900	2.9×10^{-5}
	after 24 hours	0.54	NA	1700	530	530	6.0×10^{-5}

[1]Belcher et al., 1997, MRID No. 442787-01

[2]mg/4 hour day from study

[3]Short-term

[4]Intermediate-term

[5]Long-term

[6]Not applicable

Postapplication dermal risks for farmers handling and planting treated seed are summarized in Table 12. Only short- and intermediate-term risks were estimated; long-term exposures are not expected. No chemical-specific data were available for seed handling scenarios, so exposure was estimated by assuming that the total amount of etridiazole applied to the seed is available. These risk estimates are not of concern as long as current REIs are observed.

Table 12. Dermal Exposure Risks for Farmers Handling Treated Cottonseed 12 Hours Post-Application[1]

Formulation	Application Rate[2]	Combined MOE (Dermal + Inhalation)		Cancer Risk	
		ST[3]	IT[4]	Private Farm[5]	Commercial[6]
Dust	0.05	60,000	22,000	6.8×10^{-8}	2.0×10^{-7}
Liquid	0.0625	48,000	18,000	8.4×10^{-8}	2.4×10^{-7}

[1]Due to the lack of data for seed treatment, this assessment assumed the total amount of etridiazole applied to the seed is available. Unit exposure data for handling granular formulations from PHED were used to estimate the dose.

[2]lb ai/100 lb cotton seed

[3]Short-term ($\leq$7 days)

[4]Intermediate-term (8 days to several months)

[5]7-day exposure duration

[6]20-day exposure duration

d. Incident Reports

Incidents involving exposure to etridiazole are reported in the four sources reviewed: OPP's Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), and the National Pesticides Telecommunications Network (NPTN).

Relatively few incidents involving injury from etridiazole have been reported. In one incident, a greenhouse worker potting soil as part of an exposure study reportedly became ill after handling treated soil four hours after treatment (rather than twelve hours as indicated on the label). Poison Control Center data from 1993 through 1996 indicate that the percentage of etridiazole exposure cases seen in a health care facility was only slightly above the average for all pesticides. The California Pesticide Illness Surveillance Program has received one report of illness in which etridiazole was judged to be responsible. In this case, a worker handling moist treated soil reportedly experienced eye and skin illness for two years but did not require hospitalization and was not known to take time off work due to the exposure.

B. Environmental Risk Assessment

A summary of the Agency's environmental fate and effects risk assessment is presented below. More detailed information on the environmental and ecological risks associated with the use of etridiazole may be found in the *Revised EFED Risk Assessment for the Reregistration Eligibility Decision on 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole (Etridiazole; Terrazole®), May 16, 2000.* Since that document was completed, the Agency made changes in its assessment of chronic surface water concentrations of etridiazole associated with turf use. Specifically, the Tier 1 GENEEC simulation was refined to reflect use on tees, greens and fairways only rather than an entire golf course. This revision is described in the memorandum entitled *Terrazole: Refined Tier I Chronic Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment, May 26, 2000*. The complete environmental fate and effects risk assessment and related addenda are not included in this document, but are available on the Agency's web page at *www.epa.gov/pesticides,* and in the Public Docket.

1. Fate and Transport

Etridiazole is a mobile compound with moderate persistence; these properties generally would raise concern related to the quality of groundwaters and surface waters in the proximity of treated crops. Given the low application rates for cotton, ornamental plants and seed treatment, the chemical has relatively low potential to affect the quality of such bodies of water as a result of these uses. However, turf use presents a different scenario because the application rates are very high (50 times higher than

for the other crops, up to an annual maximum total of 19 lb a.i./A) and golf courses represent particularly vulnerable use sites prone to contamination of surface waters via runoff.

The primary route of dissipation of etridiazole is volatilization and to a lesser degree aerobic soil metabolism. It is stable to hydrolysis and aqueous photolysis; however, it is somewhat susceptible to soil photolysis. Under aerobic soil metabolism conditions, etridiazole dissipates slowly. Two degradation products, 3-Carb-T and 3-DCMT, were observed in the soil photolysis and the aerobic soil metabolism studies to have properties similar to that of the parent compound.

Terrestrial field dissipation studies show that etridiazole has low to moderate persistence, with dissipation rates that appear to suggest substantial volatilization. The moderate rate of dissipation of etridiazole in the field suggests the potential for contamination of both surface and ground waters if the appropriate environmental conditions are present. The variability in the half-lives (4-33 days) seen in terrestrial field dissipation studies conducted in Texas, North Carolina and California is consistent with a compound that volatilizes.

Etridiazole may reach surface waters following rain events that produce runoff a few days to weeks after application (for two of the terrestrial field dissipation studies, the half-lives were 16 and 33 days). Since etridiazole is relatively stable to abiotic degradation (hydrolysis, aqueous photolysis), it may persist for considerable periods of time in aquatic areas with long residence times and low microbiological activity. Additionally, volatilization from water may or may not be significant depending on environmental conditions such as depth of the water, temperature, wind speed and flow rate. The actual rate of volatilization from aqueous environments is relatively slow, with a half-life of 25 days.

Two degradates (3-Carb-T and 3-DCMT) detected in laboratory studies were monitored in the field. Both degradates had high mobility in laboratory batch equilibrium studies. In the field, the degradate 3-Carb-T was persistent and mobile relative to the parent compound. The degradate 3-DCMT appeared to be somewhat persistent, but it did not leach substantially.

Etridiazole accumulated in fish with bioconcentration factors (BCFs) of 94x in edible fish tissues, 328x in viscera, and 193x in whole fish. Depuration was rapid, at 50% one day after ending exposure.

For more environmental fate and transport information on etridiazole, see the Environmental Fate Assessment section of the May 22, 2000 *Environmental Fate and Effects Risk Assessment*.

2. Water Resources

Risks to aquatic organisms were estimated using the same EECs used in the drinking water assessment, as shown in Table 7, with the exception of chronic surface water concentrations associated with application to turf. The chronic surface water EEC for turf use originally assumed application to an entire golf course. The calculation was later refined to reflect use on greens, tees and fairways only, resulting in a lower chronic EEC for turf of 32.3 ppb. This EEC is reflected in the chronic aquatic risk quotients cited below. For more information, see *Terrazole: Refined Tier I Chronic Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment,* May 26, 2000.

3. Ecological Risks

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various species. The higher the RQ the greater the concern. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies. For more information on the ecological risks posed by the use of etridiazole, see the Ecological Effects Hazard Assessment and Ecological Risk Assessment sections of the *Revised EFED Risk Assessment for the Reregistration Eligibility Decision on 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole (Etridiazole; Terrazole®),* May 22, 2000.

The ecological toxicity database for etridiazole is incomplete. Available data indicate that on an acute basis, etridiazole is practically nontoxic to birds, slightly toxic to mammals, moderately toxic to fish and aquatic invertebrates, and highly toxic to aquatic plants. On a chronic basis, etridiazole produced reproductive and growth effects in birds, fish and aquatic invertebrates. Acceptable chronic toxicity data for mammals measuring reproductive effects have not been submitted by the registrant, so a chronic risk assessment for mammals could not be conducted.

Golf course turf use is expected to pose a risk to surface water quality given the relatively high application rates for turf and the likelihood that golf course runoff will move to surface water. Etridiazole may also reach surface waters as a result of spray drift.

a. Risks to Birds

For cotton use, avian acute RQs range from <0.01 to 0.06; chronic RQs range from 0.06 to 1.82. After one application at the typical rate for turf, acute RQs range from 0.03 to 3.5. After two and five

applications at the typical rate for turf, chronic risks are of concern for birds feeding on all food items, with RQs ranging from 0.1 to 64.

In a chronic toxicity study in mallards, significant reproductive effects including reduced numbers of eggs laid, viable embryos, normal hatchlings and 14-day survivors were observed. A chronic toxicity study in bobwhite quail yielded similar results. It is uncertain whether these reproductive effects are indicative of an endocrine-mediated mode of action.

b. Risks to Mammals

After application to cotton, there are no acute risk concerns for mammals.

For turf use, acute RQs range from 0 to 2.95. After one application at the typical application rate for turf, there are acute risk concerns for small, intermediate and large mammals feeding on short grasses, tall grasses, broadleaf plants and insects. After two and five applications at the typical application rate for turf, there are acute risks for small, intermediate and large mammals feeding on short and tall grass, broadleaf plants and insects.

An assessment of chronic risks to mammals could not be conducted due to lack of appropriate toxicity data. Chronic mammalian toxicity data that will enable this assessment are being required, as discussed in Section V.A.2, Additional Generic Data Requirements, of this document.

c. Risks to Fish and Aquatic Invertebrates

Etridiazole is moderately toxic on an acute basis to both freshwater and marine fish and invertebrates. Available chronic data indicate that etridiazole produced growth effects in freshwater fish.

After application to cotton, there are no risk concerns for freshwater fish and invertebrates or for estuarine/marine fish and invertebrates.

For turf use, the acute RQs for freshwater fish range from 0.188 to 0.361; chronic RQs range from 1.41 to 2.70. For freshwater invertebrates, acute RQs are 0.05 to 0.09; chronic RQs are 0.55 to 1.05. For estuarine/marine fish, acute RQs are 0.06 to 0.11. For estuarine/marine aquatic invertebrates, acute RQs are 0.09 to 0.18. Chronic RQs were not calculated for estuarine/marine fish and invertebrates because appropriate chronic toxicity data were not available.

The degradate 3-DCMT was found to be very highly toxic to freshwater fish on an acute basis. No toxicity data are available for the degradate 3-Carb-T; however, based on its partition coefficient, 3-Carb-T is expected to be less toxic to aquatic organisms than 3-DCMT.

d. Risks to Aquatic Plants

Etridiazole was classified as highly toxic to non-target aquatic plants. Toxicity to green algae was approximately 100 times higher than other aquatic plants tested. Acute risk concerns exist at the typical application rates for turf, with RQs ranging from 0.03 to 218.00. Chronic risks were not estimated because chronic toxicity tests are not available for aquatic plants.

e. Risks to Endangered Species

There are risks to federally listed endangered and threatened birds, mammals, aquatic plants and freshwater and estuarine fish and invertebrates from single and multiple applications of etridiazole to turf.

IV. Risk Management, Reregistration and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing etridiazole as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing etridiazole. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of etridiazole.

These data were sufficient to allow the Agency to determine that etridiazole can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing etridiazole as the active ingredient are eligible for reregistration, provided specified changes are made to the label. Actions needed to reregister particular products are addressed in Section V of this document The Agency believes that these label changes address the current risk estimates and reflect the use of all acceptable data available at this time together with uncertainty factors and where data gaps exist.

In addition to the label changes specified in Section V, the registrant plans to submit data to demonstrate that surface water concentrations are not a concern and a second cancer study to more fully characterize the carcinogenic potential of etridiazole. If water data show that exposure is not of concern, and the cancer study shows no increased carcinogenic potential above that already estimated based on the rat study, then fairway use may be returned to product labels. If either the water data shows increased risk estimates or the cancer study shows increased carcinogenic potential, the registrant has agreed to voluntarily cancel the use on fairways. The registrant has also agreed to reduce the maximum application rate on golf course tees and greens, and to reduce the maximum amount applied per season.

The Agency may take appropriate regulatory action if new information comes to the Agency's attention regarding the reregistration of etridiazole. The Agency may also require the submission of additional data (1) to support the registration of products containing etridiazole, (2) if the data requirements for registration change, or (3) if the guidelines for generating such data change.

B. Tolerance Reassessment

Based on the review of the generic data for etridiazole, the Agency has sufficient information to reassess tolerances for etridiazole. Specific findings are discussed in the following section.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for etridiazole, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices and scenarios, and the environmental behavior of etridiazole. Since there are no residential or lawn uses of etridiazole, no dermal or inhalation exposure is expected in and around the home. The only non-occupational exposure source is treated golf courses, and only short-term exposures are expected to occur. Therefore, EPA has considered only acute, chronic (non-cancer), and chronic (cancer) exposures from dietary (food and drinking water) and short-term non-occupational golf course exposures in its aggregate risk assessments.

Aggregate Dietary Risks: Acute and chronic non-cancer dietary risks (food and water) are not of concern for any population subgroup, and no mitigation is necessary.

Chronic cancer dietary risks are a concern for the general population due to chronic surface water EECs associated with use on golf course tees, greens and fairways. For the cancer dietary risk assessment, the Agency has estimated the cancer dietary (food) risk to be 1.6×10^{-7} for uses supported through reregistration. The registrant has agreed to remove fairway use from product labels, to reduce the maximum application rate on golf course turf, to reduce the frequency of application, and to reduce the maximum number of pounds allowed to be applied per season. In addition, the registrant plans to provide additional data to refine exposure and carcinogenicity estimates. The reductions in area treated, and frequency and amount applied reduce the estimated chronic surface water EEC for turf use to 5 ppb, compared to a DWLOC of 1 ppb. Given that the DWLOC and EEC are derived from models using conservative exposure assumptions, and that dietary (food only) cancer risks for the general population are less than the amount the Agency considers to be negligible, the Agency does not believe that the chronic surface water EEC of 5 ppb is a risk of concern, as discussed in Section IV.E.1.d. EPA is reasonably certain that exposure to etridiazole in drinking water will result in no harm.

Short-term Aggregate Risk: Cancer aggregate risk estimates for the general population are of concern due to surface water EECs from use on golf course tees, greens and fairways. These estimates include chronic exposure to food and water and short-term non-occupational exposure to treated golf courses. The combined cancer risk estimate for food and golf course exposure, including fairways, was 1.1×10^{-6}. The registrant has agreed to remove fairway use from product labels as well as to reductions in the application rates, maximum poundage applied per season and the frequency of application, which adequately address the drinking water contribution to aggregate risk. With the reductions in area treated and amount applied discussed above and the incorporation of a new (increased) transfer coefficient derived from data obtained from the Agricultural Reentry Task Force, the cancer risk estimate for food and golf course exposure combined is 1.3×10^{-6}. This risk estimate is based on conservative, or protective, assumptions about exposure from both food and golf courses, as discussed in Section V.D.3.d. The Agency does not believe this represents a risk of concern. EPA is reasonably certain that aggregate exposure to etridiazole will result in no harm.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for etridiazole, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific

consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of etridiazole residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from etridiazole residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. An FQPA safety factor is required for etridiazole because there is no acceptable multigeneration reproduction study which could identify potential reproductive effects to the parental animals or to the offspring following pre-/postnatal exposure to etridiazole. However, the FQPA Safety Factor Committee concluded that the 10x FQPA safety factor could be reduced to 3x for the reasons discussed earlier in Section III.A.3. The FQPA safety factor of 3x is used in the chronic dietary risk assessment only and is applicable to all population subgroups.

c. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, etridiazole may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

The Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency is examining whether and to what extent thiazole pesticides share a common mechanism of

toxicity. Current information on the common mechanism of toxicity for thiazoles is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other thiazoles or carcinogenic chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that etridiazole does not share a common mechanism of toxicity with other thiazoles or carcinogenic chemicals.

D. Tolerance Summary

The established tolerances for residues of etridiazole in/on plant commodities are currently expressed in terms of etridiazole and its monoacid metabolite, 3-Carb-T. Tolerances are established in or on the following raw agricultural commodities: corn, cottonseed, tomatoes, wheat, strawberries, meat, milk, poultry, and eggs (40 CFR §180.370). Etridiazole is not currently registered for use on tomatoes or strawberries. The tolerance for strawberries is no longer being supported by the registrant and will be revoked. The registrant has committed to provide additional data in order to maintain the tolerance for tomatoes for import purposes.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of these changes, etridiazole tolerances for certain commodities which have been removed from the list will be revoked. In addition, tolerances for commodities which will not be supported for reregistration will be revoked. A summary of etridiazole tolerance reassessments is presented in Table 13.

1. Tolerances Listed Under 40 CFR §180.370

Sufficient data have been submitted to reassess the established tolerances for the following plant commodities: corn, cottonseed and wheat. The available data from field trials on cotton reflecting the maximum registered use patterns suggest that the combined residues of etridiazole and its monoacid metabolite in/on undelinted cottonseed can be lowered to 0.1 ppm. Available residue data support the tolerances at 0.1 ppm for residues in/on corn forage and fodder and wheat forage and straw.

The use of etridiazole on strawberries and tomatoes is not being supported for reregistration, and these sites do not appear on any of Uniroyal's end-use product labels that contain etridiazole as an active ingredient. Uniroyal has committed to support a tolerance for tomatoes for import purposes but not for strawberries. Consequently, the tolerance for strawberries will be revoked. Unless Uniroyal or another entity submits acceptable foreign field trial data as required to support the tolerance on tomatoes for import purposes, the established tolerance for tomatoes will be revoked.

Established tolerances in all animal commodities will be revoked. Available data suggest no reasonable expectation of finite residues (Category 3 of 40 CFR §180.6) of etridiazole and 3-Carb-T in meat, meat by-products, fat and milk of cattle, goats, hogs, horses, sheep, and in poultry, poultry fat, poultry meat by-products, and eggs. Available data suggest that even when etridiazole was applied to cotton in-furrow at 100 times the maximum application rate, there were no residues of parent or metabolite in cottonseed or foliage. In addition, data indicate that residues of etridiazole in cotton, undelinted cottonseed or cotton gin byproducts (livestock feed items) are likely to be less than the limit of quantitation.

2. New Tolerances to Be Established under 40 CFR §180.370

New tolerances are needed for etridiazole residues in/on the following raw agricultural commodities: cotton gin byproducts, peanut nutmeat and hay, sorghum grain and forage, barley grain and hay, and safflower seed. Tolerances are also needed for legume vegetables (succulent or dried), and foliage of legume vegetables. All new tolerances will be set at 0.1 ppm.

Table 13. Tolerance Summary for Etridiazole

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment *[Correct Commodity Definition]*
Tolerances listed under 40CFR § 180.370			
Corn, field, grain	0.05	0.1	Metabolism studies indicate that the tolerance for residues in/on corn grain should be increased to 0.1 ppm.
Corn, fodder	0.1	0.1	
Corn, forage	0.1	0.1	
Cotton, seed	0.2	0.1	The available data support lowering the tolerance. *Cotton, undelinted seed*
Strawberries	0.2	Revoke	The registrant is no longer supporting use on strawberries.
Tomatoes	0.15	**To Be Determined**	Etridiazole is not registered for use on domestically grown tomatoes. Tolerance to be determined based on import residue foreign field trial data (HED SOP 98.6).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment *[Correct Commodity Definition]*
Wheat, grain	0.05	0.1	Available data indicate that the tolerance for residues in/on wheat grain should be increased to 0.1 ppm.
Wheat, forage	0.1	0.1	
Wheat, straw	0.1	0.1	
Eggs	0.05	Revoke	Available data suggest no reasonable expectation of finite residues (Category 3 of 40 CFR § 180.6) of etridiazole and 3-Carb-T in livestock commodities.
Milk	0.05		
Fat, mbyp, and meat of poultry	0.10		
Fat of cattle, goats, hogs, horses, and sheep	0.10		
Meat and mbyp of cattle, goats, hogs, horses, & sheep	0.10		
Tolerances Needed under 40CFR 180.370			
Cotton, gin byproducts	None	0.1	The available data support establishing a tolerance of 0.1 ppm for residues in this group.
Vegetable, foliage of legume, group	None	0.1	Available data support establishing a 0.1 ppm tolerance on this group.
Legume vegetables (succulent or dried) crop group	None	0.1	The available data support establishing a tolerance of 0.1 ppm for residues in this group.
Barley, grain	None	0.1	Available data support a 0.1 ppm tolerance.
Barley, hay	None	0.1	
Peanut	None	0.1	
Peanut, hay	None	0.1	
Safflower seed	None	0.1	
Sorghum, grain, grain	None	0.1	
Sorghum, forage	None	0.1	

3. Codex Harmonization

No maximum residue limits for etridiazole have been established by Codex for any agricultural commodities. Therefore, there are no issues regarding compatibility with respect to U.S. tolerances.

4. Residue Analytical Methods

Plants: The current Pesticide Analytical Model (PAM) Volume II method is a GLC/ECD method (designated as Method 1) which is used for analysis of residues of etridiazole *per se* and a HPLC/UV method for determining the monoacid metabolite (designated as Method A) in/on cottonseed, corn and wheat (Pesticide Reg. Sec. 180.370). PAM Volume II reports the sensitivity of both methods (LOQ) as 0.05 ppm.

Animals: PAM Volume II does not describe any methods for enforcing tolerances for residues in animal commodities. However, two Agency-validated methods are available for tolerance enforcement: a GC/ECD method entitled, "Determination of Residues of Terrazole in Chicken Matrices," capable of quantitating etridiazole *per se* in eggs and beef liver; and a HPLC method (CAM-47-81) that determines the monoacid in eggs and beef liver. These methods should be included in future updates of PAM Volume II.

E. Human Health Risk Mitigation

As indicated previously in this document, the Agency is requiring a repeat carcinogenicity study in the mouse. The available mouse carcinogenicity study was found to be unacceptable due to technical deficiencies, but it did show the presence of gross and histological lesions in the lung, an organ where lesions did not occur in the rat study. Although a repeat mouse study had not been required previously, the Agency is now requiring a repeat of this study in order to confirm the human cancer risk estimates. Currently, the cancer risk assessment for etridiazole is based upon a relatively high Q_1* (3.3×10^{-2}) in the rat. Because the current assessment uses a conservative, or protective, set of human exposure assumptions for the dietary (food and water), non-occupational (golfer) and occupational assessments, a second cancer study is expected to confirm the results of this risk assessment and is not likely to change the outcome of the risk management decisions being made at this time.

1. Dietary Mitigation

a. Acute Dietary (Food)

The acute dietary risk estimate for the only population subgroup of concern, females 13-50, is 1% of the acute PAD, and thus is not of concern (see Table 3). An acute toxicity endpoint was not identified for any other population subgroup. Therefore, no mitigation measures are necessary to address acute dietary risk from food.

b. Chronic (Non-Cancer) Dietary (Food)

Chronic non-cancer dietary risk from food is also not of concern. Chronic non-cancer dietary risk for the most exposed population subgroup, children 1-6 years of age, is 31% of the chronic PAD; for the

general U.S. population, exposure estimates account for 14% of the cPAD (see Table 4). These risks are not of concern; therefore, no mitigation measures are necessary to address chronic dietary risk from food.

c. Cancer Dietary (Food)

The Agency generally considers $1x10^{-6}$ (1 in 1 million) or less to be negligible risk for cancer. The results of this analysis indicate that the cancer dietary (food only) risk of 1.6×10^{-7} is not of concern (see Table 5). Therefore, no mitigation measures are necessary to address cancer dietary risk from food.

d. Dietary (Drinking Water)

Model estimates (EECs) of potential drinking water exposure from ground water sources do not exceed the acute or chronic (non-cancer and cancer) DWLOC values, and therefore, are not of concern. Similarly, potential drinking water exposure from surface water after application to cotton does not exceed the acute or chronic (non-cancer and cancer) DWLOC values, and thus is not of concern. Potential exposure from surface water sources after application to golf course tees, greens and fairways is not of concern for acute or chronic (non-cancer) dietary risk. However, potential exposure from surface water sources after application to golf course tees, greens and fairways is of concern for chronic (cancer) dietary risk (see Table 6).

The modeled estimate of 56-day average concentrations in surface water associated with use on golf course fairways, tees and greens is 32.3 ppb. This exceeds the cancer DWLOC of 1 ppb for the general population, and thus is of concern. To address this risk, the registrant has agreed to immediately remove use on fairways from product labels, thus limiting use to tees and greens only, to reduce the maximum application rate to 3.8 lbs ai/A, increase the minimum interval between applications to 10 days, and reduce the maximum amount applied per season to 9.6 lbs ai/A. In addition, the registrant plans to submit data to demonstrate that surface water concentrations are not a concern and to more fully characterize the carcinogenic potential of etridiazole. If water data show that exposure is not of concern, and the second cancer study shows no increased carcinogenic potential above that already estimated based on the rat study, then fairway use may be returned to product labels. If either water data shows increased risk from drinking water exposure or the cancer study shows increased carcinogenic potential, the registrant has agreed to voluntarily cancel the use on fairways.

When treatment of fairways is removed from the modeled estimates and the reductions in rate, frequency and seasonal maximum poundage are considered, the surface water concentration is estimated to be approximately 5 ppb. Despite the fact that the estimated concentrations in surface water of 5 ppb slightly exceed the estimated DWLOC of 1 ppb, the Agency does not believe this is a risk of concern for the following reasons:

1) The EECs were derived from a screening level model (GENEEC) developed for use in ecological assessments to estimate risks to aquatic organisms. At present, PRZM/EXAMS, the Tier II model, does not have the appropriate parameters to accurately model turf runoff. Although GENEEC is not an ideal tool for use in drinking water assessments, it can provide high-end estimates of the concentrations that might be found in a confined farm pond. Surface water source drinking water does not typically come from this type of scenario, but rather from bodies of water that are substantially larger than such ponds and from diverse watersheds. Unlike a confined pond, there is always some flow (in a river) or turnover (in a lake or a reservoir) resulting in an overestimation of the persistence of the chemicals near the drinking water utility intakes. Additionally, contaminated surface water used for drinking water would undergo dilution and some treatment prior to consumption, likely further reducing the levels of etridiazole.

2) The GENEEC model uses the 56-day average of pesticide concentrations after the application of the pesticide, as opposed to the 36-year mean provided by PRZM/EXAMS. This short time period may not adequately characterize a person's average daily exposure over a year.

3) This EEC is the result of refinements to the GENEEC model. The refinements include the incorporation of a percent crop area (PCA) factor of 17% as described in Section III.A.7.a. It is likely that the assumption that 17% of the area in a watershed is tees and greens is a conservative assumption. In addition, exposure from application to tees and greens only is not likely to be widespread.

4) To estimate the DWLOC, exposure from food and non-occupational sources combined are subtracted from the PAD; the difference represents the theoretical upper limit of exposure from water in light of total aggregate exposure from food, water and non-occupational uses that will result in no adverse health effects. To estimate exposures from food, the Agency assumed residue levels of one-half the combined LOQs for all commodities grown from treated seed except tomatoes, and tolerance level residues for tomatoes. However, available field trial data indicate that residues on commodities grown from treated seed are unlikely to occur at current application rates. Therefore, the amount of exposure from food used in the calculation is likely an overestimate, with the result that the DWLOC of 1 ppb is likely to be underestimated.

2. Non-occupational Risk Mitigation

a. Non-occupational Non-cancer Risk

The only non-occupational exposure expected to occur is short-term exposure to golfers. For the only population subgroup of concern, females 13-50 years of age, the MOE is 17,000, which is not a risk concern. Therefore, no mitigation is necessary.

b. Non-occupational Cancer Risk

The estimated cancer risk for adult golfers exposed to treated golf course tees, greens and fairways was 8.9×10^{-7}. This calculation, presented in the June 6, 2000, *Human Health Risk Assessment*, used a transfer coefficient of 100. Since that time, the Agency has received data from the Agricultural Reentry Task Force indicating that a more appropriate transfer coefficient for assessing risk from golf course exposures is 500. In recalculating the risk to golfers to reflect removal of fairways and therefore exposure to tees and greens only, the Agency also applied the new transfer coefficient of 500. The resulting cancer risk estimate for adult golfers exposed to tees and greens only is 1.1×10^{-6}. This risk assumes that a golfer who plays golf 18 times per year is exposed 18 times per year, within 12 hours after application, over a period of 50 years. The Agency believes that the estimated cancer risk is an overestimate due to these conservative assumptions used in the assessment. A more realistic estimate assumes that a golfer would likely receive two exposures per year, the typical number of applications of etridiazole per season. When two exposures are assumed, the resulting cancer risk to golfers is estimated to be 1.2×10^{-7}, which is not of concern.

3. Aggregate Risk Mitigation

a. Acute Aggregate Risk

Estimated acute risk for etridiazole for food is 1% of the aPAD, and surface and groundwater acute EECs are below the DWLOC for the population subgroup assessed (females 13-50 years old). Thus, acute risk from food and water is not of concern and no mitigation is necessary.

b. Short-term Aggregate Risk

In order to determine the short-term aggregate risk, the Agency combines the short-term risks from any non-occupational exposures, in the case of etridiazole it is the risk to golfers, with the risks from food and drinking water. The only short-term toxicity endpoint identified for etridiazole was for females 13 to 50 years of age; consequently, the short-term aggregate risk is calculated only for this subpopulations. Since the Agency does not have any reliable monitoring data from which to estimate the exposures in water, it had to rely on the DWLOC method to determine if the risk cup is exceeded. The short-term risk for golfers (expressed as a margin of exposure) was estimated to be 17,000. The short-term dietary risk for food for the subpopulations of concern was estimated to be 0.4%, equivalent to an MOE of 28,000. (The Agency assumes that the chronic exposure from etridiazole residues in food is equal to the short-term exposure.) By adding the exposures associated with these risks, comparing them to the short-term toxicological endpoint (i.e., a NOAEL of 15 mg/kg/day), and determining the amount of room left in the risk cup, one can determine the level of residues in drinking water that would be allowed (the DWLOC) before the cup is full. In this instance, it was determined that drinking water could contain up to 4300 ppb before there is a risk of concern (i.e., a margin of exposure of less than 100). The Agency did not model for short-term exposures from drinking water

but instead used the model estimate for surface water acute exposures for comparison to the DWLOC. This is a conservative estimate since the level of residues in drinking water to which a person could be exposed over a short-term period would be expected to be less than the maximum (or acute) level to which one could be exposed. The short-term DWLOC was estimated to be 4300 ppb, while the estimated acute exposure was modeled to be 230 ppb. It should be noted that the risk calculated for the golfer included exposure to fairways. The registrant has agreed to remove fairway use from product labels which will reduce exposure, increase the MOE and increase the DWLOC. This coupled with the use of the acute exposure value modeled for drinking water leads the Agency to believe this is a conservative assessment of short-term aggregate risk. Therefore, short-term aggregate risks are not a concern, and no mitigation is necessary.

c. Chronic (Non-Cancer) Aggregate Risk

Chronic (non-cancer) aggregate risk for etridiazole includes only food and water exposures. Estimated risks from food for the most highly exposed subgroup, children 1-6, indicate that 31% of the cPAD is occupied by dietary (food) exposure and that surface and ground water EECs (32.3 ppb and 0.93 ppb, respectively) are below the chronic DWLOC for this population subgroup (35 ppb). Therefore, chronic non-cancer aggregate risks are not a concern, and no mitigation is necessary.

d. Chronic Cancer Aggregate Risk

Cancer aggregate risk is a concern for the general population due to surface water EECs associated with turf. Estimated cancer risk from food and exposure to treated golf courses, including fairways, was $1.1x10^{-6}$. The registrant has agreed to immediately remove fairway use from labels, reduce the maximum application rate, the maximum poundage applied per season, and the frequency of application. In recalculating the risk to golfers to reflect the removal of fairways, the Agency also applied the new transfer coefficient of 500. The resulting cancer risk estimate for adult golfers exposed to tees and greens is $1.3x10^{-6}$. The cancer risk estimate for golf course exposure assumes exposure to the full amount applied, 18 times per year for 50 years. As indicated previously, a more realistic estimate of the number of exposures to a golfer is two per year; when two exposures are assumed, the resulting cancer risk estimate is $1.2x10^{-7}$. When combined with the cancer risk from food, this results in a cancer aggregate risk estimate of $2.8x10^{-7}$, which is not of concern.

The estimated drinking water exposure from treated golf courses, including fairways, is 32.3 ppb. This exceeds the cancer DWLOC of 1 ppb and is of concern. The estimated surface water EEC resulting from use on tees and greens only, at the reduced application rate, assuming the maximum amount applied and maximum frequency of application, is 5 ppb. Given the conservative assumptions on which the EEC and DWLOC are based, the Agency does not believe that this represents a risk of concern. This is discussed in greater detail above in the Section IV.E.1.d on mitigation of drinking water risks.

4. Occupational Risk Mitigation

a. Handler Exposure

1) Overview

There are potential occupational exposures to pesticide handlers via the dermal and inhalation routes when applying etridiazole. Scenarios assessed and corresponding risk estimates are shown in Table 9. The footnotes indicate the level of protection (PPE or engineering controls) needed to bring the risk estimate to a level that is not of concern (MOE of 100 or greater, and cancer risk of $1x10^{-6}$ or less). In some cases these measures exceed what is specified on current labels. Risks for some scenarios are of concern even when maximum PPE is applied, indicating a need for engineering controls. However, in some of these scenarios, engineering controls are not available. Therefore, mitigation measures necessary for etridiazole include a combination of increased PPE, use site deletions, prohibition of hand-held spreaders, and reduced application rates. Specific measures are presented in greater detail below.

Some uncertainty exists around inhalation toxicity and exposure for handlers and postapplication workers. All margins of exposure were derived from PHED. The combined dermal and inhalation MOEs were not significantly different from the dermal MOE, suggesting that occupational handler risks are largely due to estimated dermal exposures. However, these MOEs are likely to underestimate inhalation exposures. The vapor pressure of etridiazole is higher than the mean vapor pressure of chemicals in PHED, so actual inhalation risks are expected to be higher than indicated by the calculated inhalation MOEs. In addition, a chemical-specific postapplication exposure study in workers handling treated potting soil found that approximately 70% of the total dose was due to inhalation. In calculating inhalation risk estimates, the Agency used protective assumptions about the amounts handled and number of exposures, and applied a 100% inhalation absorption factor.

The inhalation risk estimates indicate that an OV respirator provides the protection needed to bring handler inhalation risk to a level that is not of concern. Therefore, the Agency has determined that, unless closed systems are used, an OV respirator is necessary for all handlers for all uses except when applying in-furrow to cotton. Due to the type of application, the Agency believes that inhalation risks to handlers for in-furrow application are expected to be negligible. Current labels do not specify an OV respirator, and the registrants have agreed to add this to the labels. Additional inhalation data are being required as part of this RED, and are expected to confirm the current risk estimates.

EPA considers occupational cancer risks of $1x10^{-6}$ (1 in 1 million) and less to be negligible. In addition, the Agency generally examines occupational risks in the range of $1x10^{-6}$ to $1x10^{-4}$ to determine the feasibility and cost of additional mitigation and seeks ways to mitigate these risks. This policy allows for the consideration of a wide range of factors in making a risk management decision for occupational risks. These factors may include: risk to individuals, number of people exposed, weight of scientific

evidence regarding carcinogenicity, and lower risk alternatives. EPA seeks to reduce the individual risks to the greatest extent feasible, preferably to $1x10^{-6}$ or less. The goal is to ensure that there is a minimum level of protection from exposure to pesticide for workers. Through the reregistration process, the Agency will specify, as appropriate, additional protective clothing or equipment or changes in application methods.

Current product labels vary widely in the amount of personal protection specified. The registrants have agreed to the measures discussed in this document and labels will be amended accordingly. For some products, the measures agreed to by the registrants represent an increase over what is currently on the labels. For others, the level of protection necessary is less than that now on labels.

While the above discussion encompasses all uses of etridiazole, the remainder of the discussion on mitigation measures will be presented by use site.

2) Cancelled Uses/Formulations

Flowable concentrate

To address risks associated with use of the flowable concentrate formulation, the registrant has requested voluntary cancellation of this formulation. The Agency published the proposed cancellation for public comment in the *Federal Register* on September 6, 2000 (Vol. 65, Number 173).

Granular formulation for use on golf courses

The registrants have agreed to remove fairway use from product labels immediately, limiting use of etridiazole on golf courses to tees and greens. They have also agreed to explicitly state on product labels that application of granulars with a push-type spreader, belly grinder, power dust blower or hand dispersal is not allowed. The result is that no feasible application method for application of the granular formulation to tees and greens remains. Therefore, the registrants have agreed to request a voluntary cancellation of the granular formulation registered for use on golf course turf.

1) Seed Treatment

All handlers

No chemical-specific data were available for assessing handler exposure for seed treatment use. Uncertainties exist around dermal and inhalation exposure and toxicity of etridiazole. Inhalation exposure is a particular concern when considering risks associated with indoor use. To address these uncertainties, the registrant has agreed to specify closed systems for all seed treatment activities as well as the use of chemical-resistant gloves and an OV respirator.

1) Golf Course Use

All handlers

Mixing/loading **wettable powder** for groundboom application to golf course tees, greens and fairways results in MOEs ranging from 7 to 87 and cancer risks between 10^{-4} and 10^{-5} with double-layer clothing, chemical-resistant gloves, and organic-vapor (OV) respirator. The addition of engineering controls results in MOEs of 100 or greater but cancer risks remain of concern.

To address these risks, the registrant has agreed to remove use on fairways from labels and to reduce the maximum application rate, the frequency of application and the maximum poundage allowed to be applied per season to tees and greens. These reductions result in intermediate-term MOEs of 102 and 95 and cancer risks of 10^{-5}-10^{-7} with double-layer clothing, chemical-resistant gloves and an OV respirator, which are not of concern.

To address cancer risks for mixing/loading **wettable powder** for chemigation for use on turf, the registrant has agreed to specify double-layer clothing, chemical-resistant gloves and an OV respirator, which results in MOEs greater than 100 and cancer risks of 10^{-6}-10^{-7}, which are not of concern.

To address risks associated with loading/applying **granules** to turf with a belly grinder (short-term MOE of 35, intermediate-term MOE 13, cancer risks between 10^{-4} and 10^{-6}) and push-type spreader (short-term MOE of 53, intermediate-term MOE of 20, cancer risks between 10^{-4} and 10^{-6}), the registrant has agreed to request voluntary cancellation of the granular formulation for use on turf.

In summary, mitigation for all handlers for golf course use is as follows:

- Fairway use will be removed from product labels immediately.
- The maximum application rate will not exceed 3.8 lbs ai/A.
- The interval between applications will be no less than 10 days.
- The maximum amount applied per season will not exceed 9.6 lbs ai/A.
- Double-layer clothing, chemical-resistant gloves and an OV respirator are needed for all handlers.
- Granular products registered for use on golf courses will be voluntarily cancelled.

5) Nursery (Outdoor) Use

Mixing/loading/applying

For mixing/loading/applying **EC** in-furrow to nursery soil, chemical-resistant gloves are needed to address short- and intermediate-term MOEs and cancer risks. The resulting MOEs are greater than 100 and cancer risks are 10^{-6}-10^{-7}, which are not of concern.

For mixing/loading/applying **EC** as a drench with a low-pressure handwand, chemical-resistant gloves are needed to address intermediate-term MOEs and cancer risks. The resulting MOEs are greater than 100 and cancer risks are 10^{-7}-10^{-8}, which are not of concern.

For mixing/loading/applying **EC** as a drench with a high-pressure handwand, double-layer clothing, chemical-resistant gloves and an OV respirator are needed to address cancer risks. The resulting private cancer risk estimate is 10^{-6}, while the commercial cancer risk estimate is 10^{-5}, which is acceptable in this case.

To address risks associated with mixing/loading/applying **granules** in-furrow to nursery soil, chemical-resistant gloves and an OV respirator are needed for all handlers. The resulting MOEs are greater than 100 and cancer risks are less than 10^{-6}.

To address risks associated with loading/applying **granules** with a belly grinder, power dust blower and push-type spreader, the registrant has agreed to state on product labels that these application methods are not allowed. With double-layer clothing, chemical-resistant gloves and an OV respirator, short- and intermediate-term MOEs for these methods range from 3-15, and cancer risks are 10^{-4}. Loading/applying **granules** with a power dust blower could not be assessed because no data are available for assessing this scenario. To address this uncertainty, the registrant has agreed to state on product labels that this application method is not allowed. Applying **granules** by hand with double-layer clothing, chemical-resistant gloves and an OV respirator results in margins of exposure of 13 (short-term) and 4.9 (intermediate-term) and cancer risks of 10^{-5}. To address these risks, the registrant has agreed to state on product labels that this application method is not allowed.

To address cancer risks for loading/applying **granules** (5% ai formulation) with a tractor-drawn spreader at the maximum application rate, chemical-resistant gloves are needed. With gloves the resulting cancer risks are 10^{-6}. The registrants have agreed to reduce the granular application rate for potting soil treatment to address postapplication cancer risks. This reduction will also reduce risks to handlers. This reduction is discussed in greater detail below in the section on Postapplication Risk Mitigation.

In summary, mitigation needed to address handler risks for nursery use:

EC formulation

- For use with a high-pressure handwand, double-layer clothing, chemical-resistant gloves, and an OV respirator are needed.
- For all other application methods, chemical-resistant gloves and an OV respirator are needed.

Granular formulation

- Application by belly grinder, push-type spreader, power dust blower and by hand dispersal will be explicitly not allowed on the labels.

- For all handlers, chemical-resistant gloves and an OV respirator are needed.

6) Greenhouse/Potting Soil Use

Mixing/loading/applying
To address uncertainties about indoor handler exposures, chemical-resistant gloves and an OV respirator are needed for mixing/loading/applying **granules** to potting soil.

For mixing/loading/applying **wettable powder** to potting soil, chemical-resistant gloves and an OV respirator are needed. The resulting MOEs are greater than 100 and cancer risks are 10^{-7}.

In addition, continuous ventilation is needed during indoor handling of etridiazole or etridiazole-treated media, including soil and water, as described in Section V.

In summary, mitigation needed for greenhouse use and use with potting soil are as follows:

All formulations
- Chemical-resistant gloves and an OV respirator are needed for all handlers.
- Active continuous ventilation as described in Section V is needed for all indoor use.

7) Cotton Use

All Formulations
To address MOEs and cancer risks for mixer/loaders for in-furrow application of EC or granules to cotton, chemical-resistant gloves and an OV respirator are needed. Resulting MOEs are greater than 100 and cancer risks are 10^{-6}-10^{-7}. For in-furrow applicators, only chemical-resistant gloves are needed.

b. Post-Application Exposure

Postapplication worker risks associated with turf, seed treatment and cotton uses of etridiazole are not of concern as long as the current REIs of 12 hours are retained.

For nursery and greenhouse workers handling treated potting soil, however, cancer risks based on dermal and inhalation exposure are estimated to be 2.9×10^{-5} after 12 hours postapplication, and 6.0×10^{-5} after 24 hours postapplication. To mitigate this risk, the application rate for mixing granular products with potting soil will be reduced to the lowest possible level that will still maintain efficacy of the products. For the 3% granular, the maximum application rate will be reduced from 16 oz. per cubic

yard to 12 oz. per cubic yard. The maximum application rate for the 5% granulars will be reduced from 10 oz. per cubic yard to 8 oz. per cubic yard.

In addition, continuous mechanical ventilation is needed during all indoor postapplication work involving etridiazole-treated media including soil and water, as described in Section V. Given this mitigation, the current 12-hour REI for nursery and greenhouse use will be retained.

c. Dermal and Inhalation Toxicity and Exposure Uncertainties

The Agency is concerned about inhalation exposure to etridiazole, particularly in enclosed areas such as greenhouses. Etridiazole has a relatively high vapor pressure, and the data from a chemical-specific postapplication study indicate the majority of exposure to postapplication workers handling treated soil was by the inhalation route. Further, this exposure is most likely to occur in a greenhouse where inhalation hazards may be greater than outdoors. This, coupled with the lack of inhalation toxicity and chemical-specific handler exposure data, raises concerns for both handlers and postapplication workers. In addition, a chemical-specific subchronic dermal toxicity study and a dermal penetration study would enable refinement of dermal risk estimates and help characterize cancer risks. The Agency has used protective assumptions in its risk calculations including a 3x uncertainty factor applied to the chronic NOAEL and 100% dermal and inhalation absorption factors. Thus, while the Agency believes that the level of personal protection equipment including the organic-vapor respirator that has been agreed to by the registrant adequately addresses handler risks, it is calling in additional data to confirm these risk estimates.

The following confirmatory data are required:

- 830.7950 Vapor pressure (of the dry formulations, in order to determine if handling dry formulations present a significant respiratory hazard)
- 870.3200 21-day dermal toxicity study
- 870.3465 28-day inhalation toxicity study
- 870.7600 Dermal penetration study in rats
- 875.1200 Guideline applicator study data for dermal exposure: indoors
- 875.1400 Guideline applicator study data for inhalation exposure: indoors

5. Environmental Risk Mitigation

a. Birds

In-furrow application to cotton presents no risk concerns for birds.

Turf use results in acute and chronic avian risks of concern, with RQs ranging from 0.1 to 64. The deletion of fairway use results in an 88% reduction in area treated when compared with the current

labeled use. In addition, the registrant has agreed to reduce the maximum application rate on tees and greens, the frequency of application and the maximum amount applied per season. These restrictions will mitigate both acute and chronic risks. Fairways provide more feeding opportunities for a variety of bird species than do tees and greens; therefore, limiting use to tees and greens further mitigates avian risks.

b. Mammals

In-furrow application to cotton presents no acute risk concerns for mammals.

For turf use, acute RQs range from 0 to 2.95. After one application at the typical application rate for turf, there are acute risk concerns for small, intermediate and large mammals feeding on short grasses, tall grasses, broadleaf plants and insects. After two and five applications at the typical application rate for turf, there are acute risks for small, intermediate and large mammals feeding on short and tall grass, broadleaf plants and insects. As indicated above, the Agency believes that the removal of fairway use and reductions in maximum application rate, amount applied per season and frequency of application will greatly reduce risk by minimizing exposure.

An assessment of chronic risks to mammals could not be conducted due to lack of appropriate toxicity data. Chronic mammalian toxicity data that will enable this assessment are being required, as discussed in Section V.A.1, Additional Generic Data Requirements, of this document.

c. Fish and Aquatic Invertebrates

Etridiazole is moderately toxic to both freshwater and marine fish and invertebrates. Available data indicate that etridiazole produced chronic growth effects in freshwater fish.

Application to cotton presents no risk concerns for freshwater fish and invertebrates or for estuarine/marine fish and invertebrates.

For turf use, the acute RQs for freshwater fish range from 0.188 to 0.361; chronic RQs range from 1.41 to 2.70. For freshwater invertebrates, acute RQs are 0.05 to 0.09; chronic RQs are 0.55 to 1.05. For estuarine/marine fish, acute RQs are 0.06 to 0.11. For estuarine/marine aquatic invertebrates, acute RQs are 0.09 to 0.18. As indicated above, the Agency believes that the removal of fairway use and reductions in maximum application rate, amount applied per season and frequency of application will adequately address these risks. In addition, by prohibiting use on fairways, the fairways themselves will act as buffer zones between treated tees/greens and surface water areas.

The degradate 3-DCMT was found to be very highly toxic to freshwater fish on an acute basis. No toxicity data are available for the degradate 3-Carb-T; however, based on its partition coefficient, 3-Carb-T is expected to be less toxic to aquatic organisms than 3-DCMT. Risk quotients were not

calculated for the degradates due to a lack of data. Because the registrant has agreed to remove fairway use from product labels, these data requirements are being held in reserve status at this time. Should the Agency determine in the future that fairway use can be returned to product labels, acute toxicity data for both degradates for estuarine/marine fish and invertebrates and freshwater fish and invertebrates will be required.

d. Aquatic Plants

Etridiazole was classified as highly toxic to non-target aquatic plants. Toxicity to green algae was approximately 100 times higher than other aquatic plants tested. Acute risk concerns exist at the typical application rates for turf, with RQs ranging from 0.03 to 218. As indicated above, the Agency believes that the removal of fairway use and reductions in the maximum application rate, amount applied per season and frequency of application will greatly minimize the potential for exposure. In addition, by prohibiting use on fairways, the fairways themselves will act as buffer zones between treated tees/greens and surface water areas.

e. Summary of Environmental Risk Mitigation

These ecological risk estimates associated with turf use assume use on golf course tees, greens and fairways. The registrant has agreed to delete fairway use from product labels, thereby reducing the area treated by approximately 88%. In addition, they have agreed to reduce the maximum application rate, the frequency of application, and the maximum amount applied per season. The registrant has agreed to submit additional water data to refine these risk estimates. The Agency believes that removal of fairway use from product labels in the interim period during which water data are developed is appropriate to mitigate these risks.

Based on etridiazole's persistence and mobility, the following advisory language is needed for all etridiazole product labels:

Surface Water Label Advisory
"Etridiazole can contaminate surface water through spray drift. Under some conditions, etridiazole may also have a high potential for runoff into surface water for several weeks post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlaying tile drainage systems that drain surface water."

F. Other Label Statements

Other use and safety information needed for labeling of all end-use products containing etridiazole are indicated in Table 15.

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future *Federal Register* notice. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program..

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. Interim mitigation measures are necessary for aerial applications that should be placed on product labels/labeling as specified in Section V of this document. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, the following spray drift related language is needed.

For products that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method, the following must be added to the labels:

"Do not allow this product to drift"

3. For Commercial Use Only

Etridiazole is currently registered for use on golf course turf only; use on home lawns, sod farms and municipal parks is prohibited. All product labels will be amended to state clearly "for commercial use only."

V. Actions Required of Registrants

A. Manufacturing Use Products

1. Water Exposure Data Requirements

As discussed previously in this document, estimated surface water concentrations of etridiazole were derived from a Tier 1 screening-level model that is not intended for modeling concentrations after application to turf. The registrant has agreed to submit, by March 31, 2001, refined estimates of chronic surface water concentrations for etridiazole derived from a Tier 2 PRZM/EXAMS model modified for turf applications. The adequacy of the model as well as the results of the modeling will be considered together with the results of a repeat oncogenicity study in mice. If, after evaluation of the results of both the water model and the oncogenicity study, the Agency believes that etridiazole residues in surface water are not of concern, fairway use may be returned to product labels. If fairway use is returned to product labels, ecotoxicity data on the degradates 3-Carb-T and 3-DCMT will be required. The registrant has agreed to voluntarily cancel the fairway use if the Agency finds that the risks remain of concern.

2. Additional Generic Data Requirements

The generic database supporting the reregistration of etridiazole for the eligible uses has been reviewed and determined to be substantially complete. The following confirmatory data are required:

Guideline Test Name	OPPTS Guideline No.	Old Guideline No.
UV/Visible Absorption	830.7050	none
Directions for use	860.1200	171-3
Foreign crop field trials (tomatoes)	860.1500	171-4(k)
Oncogenicity (mouse)	870.4200	83-2(b)
Dermal penetration in rats	870.7600	85-3
21-day dermal toxicity	870.3200	82-2
28-day inhalation toxicity	870.3465	82-4
Applicator dermal exposure: indoors	870.1200	233
Applicator inhalation exposure: indoors	870.1400	234
Estuarine/marine fish acute toxicity using the degradate 3-DCMT	850.1075	72-3(a)

Guideline Test Name	OPPTS Guideline No.	Old Guideline No.
Estuarine/marine invertebrate acute toxicity using the degradate 3-DCMT	850.1035	72-3(b)
Freshwater fish acute toxicity using the degradate 3-Carb-T	850.1075	72-1
Freshwater invertebrate acute toxicity using the degradate 3-Carb-T	850.1010	72-2
Freshwater invertebrate acute toxicity using the degradate 3-DCMT	850.1010	72-2

Product Chemistry

Current directions for use and UV/visible absorption data are required for the 98.6% T/TGAI. In addition, the registrants must either certify that the suppliers of beginning materials and the manufacturing process for the etridiazole technical product have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

Residue Chemistry

Additional residue data, as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required reflecting the use of etridiazole on tomatoes grown outside of the United States in order to reassess a tolerance for tomatoes. The registrant has expressed their intent to maintain a tolerance for tomatoes, and has committed to submit the required data. Should the registrant decide against submitting the required data, the current tolerance for tomatoes will be revoked.

Health Effects

There are several data gaps for the current Subdivision F Guideline requirements for a food-use chemical (40 CFR Part 158.340). These include a repeat multigeneration reproduction study in rats (protocol to include early thyroid measurements due to a concern for endocrine activity); a repeat chronic toxicity study in dogs; and a repeat carcinogenicity study in mice. The requirement for additional neurotoxic studies (i.e., delayed neurotoxicity study in the hen, acute neurotoxicity study, subchronic neurotoxicity study and/or developmental neurotoxicity study) is placed in reserve status pending submission and evaluation of a repeat multigeneration reproduction study in rats and a chronic toxicity study in dogs.

A 28-day inhalation toxicity study in rats that assesses all the parameters required in the testing guidelines for the 90-day inhalation study is required to provide inhalation toxicology endpoints for non-cancer occupational and non-occupational inhalation risk assessment.

A 21-day dermal toxicity study in rats is required. In addition, a dermal penetration study in rats will help to fully characterize dermal cancer risks.

Indoor Applicator Exposure
Due to the relatively high vapor pressure of etridiazole and the data from the submitted soil handling study that indicate the majority of soil handler exposure was by the inhalation route, the Agency is concerned about handler exposure to etridiazole, particularly in enclosed areas such as greenhouses. Therefore, the Agency is requiring product chemistry data on the vapor pressure of the dry formulations in order to determine if handling dry formulations presents a significant respiratory hazard. In addition, indoor dermal and inhalation handler exposure studies are required.

Environmental Fate and Ecological Effects
The environmental fate database for etridiazole is mostly complete, and adequate for risk assessment. However, due to the lack of chronic mammalian toxicity data using the parent compound, a chronic risk assessment for mammals could not be conducted. These data are required in order to fully characterize risks to ecological resources.

Ecotoxicity data for the degradates 3-Carb-T and 3-DCMT for aquatic organisms were not available, so risks associated with the degradates could not be assessed. Because the registrant has agreed to remove fairway use from product labels, these data are not being required at this time. Should the Agency determine in the future that fairway use can be returned to product labels, acute toxicity data for both degradates for estuarine/marine and freshwater fish and invertebrates will be required.

3. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in the table at the end of this section. The MUP label will explicitly prohibit use of products that do not conform to Section V.B.2 of this document.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

In order to more fully characterize exposure and risk to pesticide applicators due to inhalation when handling the dry formulations of etridiazole (wettable powder, granular, dust), the Agency is requiring vapor pressure data for the dry formulations.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section V above. Specific language to implement these changes is specified in Table 15 at the end of this section. The registrants have agreed to submit, not later than November 17, 2000, a complete application for amendment of each of the end-use products containing etridiazole for use on golf course fairways that are contained in Appendix A of this document. Such application must indicate use on golf course tees and greens only, and reflect all of the other mitigation measures agreed upon as indicated in this document. Should the registrants fail to submit such application for any product currently registered for use on fairways within the timeframe specified herein, the Agency may issue a Notice of Intent to Cancel that product. To remain in compliance with FIFRA, end-use product (EUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies.

C. Labeling Changes Summary Table

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Manufacturing Use Products		
Required on all MUPs	Only for formulation into fungicide products intended for the following use(s): registrants insert uses that are being supported by MP registrant]." This product may not be formulated into products intended for residential consumer use.	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	
End Use Products Intended for Occupational Use (WPS and non-WPS)		
Handler PPE for all formulations	For **sole-active-ingredient** end-use products that contain etridiazole, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed. For **multiple-active-ingredient** end-use products that contain etridiazole, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.	

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Handler PPE Requirements for Wettable Powder Formulations	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [registrant inserts correct material]. For more information, follow instructions in Supplement Three of PR Notice 93-7. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." " Loaders, applicators, and other handlers involved in dry applications to potting soil must wear: – long-sleeved shirt and long pants, – socks and shoes, – chemical-resistant gloves – NIOSH-approved respirator with: - an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH-approved respirator with an OV cartridge or canister with any N^2, R, P or HE prefilter "All other mixers, loaders, applicators and handlers must wear: – coveralls over long-sleeved shirt and long pants, -- chemical-resistant gloves, – chemical-resistant footwear plus socks, -- NIOSH approved respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH approved respirator with an OV cartridge or canister with any N^2, R, P or HE prefilter" -- chemical-resistant apron when mixing, loading, cleaning equipment.	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Handler PPE requirements for WP Formulations (cont'd)	For use in tobacco floatbeds, application is continuous from the time this product is diluted and pots or plant materials are immersed in the floatbeds through the time the pots or plant materials are removed from the floatbeds and replanted. During the entire application period, any person who contacts the floatbed, the diluted pesticide solution, treated pots, or treated plant materials is defined as a handler under the Worker Protection Standard and must be trained as a handler and wear the PPE required for handlers on the main Terrazole label. The 12-hour REI begins once the plant materials are replanted.	Directions for Use for the 24(c) Label
Handler PPE requirements for Dust Formulations	"Mixers, loaders, and applicators must wear: – coveralls over long-sleeved shirt and long pants, -- chemical-resistant gloves, -- NIOSH approved respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), - or a NIOSH approved respirator with an OV cartridge or canister with any N^2, R, P or HE prefilter"	

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Handler PPE Requirements for Granular Formulations	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [registrant inserts correct material]. For more information, follow instructions in Supplement Three of PR Notice 93-7. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." " Loaders, applicators and other handlers must wear: – Long-sleeved shirt and long pants, and – Socks and shoes In addition, all handlers, except for applicators applying in-furrow to cotton, must wear: -- Chemical-resistant gloves, and -- NIOSH- approved respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH approved respirator with an OV cartridge or canister with any N^2, R, P or HE prefilter"	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Handler PPE Requirements for Liquid (EC) Formulations[1]	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [registrant inserts correct material]. For more information, follow instructions in Supplement Three of PR Notice 93-7. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, and applicators participating in high-pressure handwand sprayer applications must wear: – coveralls over long-sleeved shirt and long pants, -- chemical-resistant gloves, – chemical-resistant footwear plus socks, -- chemical-resistant headgear for overhead applications, -- NIOSH approved respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), - or a NIOSH approved respirator with an OV cartridge or canister with any N^2, R, P or HE prefilter" -- chemical-resistant apron when mixing, loading, or cleaning equipment. "All other mixer, loaders, applicators and other handlers must wear: – long-sleeved shirt and long pants, -- chemical-resistant gloves, -- NIOSH approved respirator (except for applicators applying in-furrow to cotton) with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH approved respirator with an OV cartridge or canister with any N^2, R, P or HE prefilter	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
User Safety Requirements for EC and Wettable Powder Formulations	"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Requirements for Granular Formulations	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Engineering Controls	"Engineering Controls" "For all seed treatments, handlers must use a closed mixing, loading, and application system designed by the manufacturer to enclose the pesticide in a manner that prevents it from contacting (dermally or through inhalation) handlers or other people during the entire seed treatment process. The system must be: - entirely mechanized, so the only contact handlers have is with the unopened pesticide container while they place it into the system, with the reclosed or empty container when it is removed from the system, and with the bags containing the treated seed, - functioning properly, and - used and maintained in accordance with the manufacturer's written operating instructions. Handlers participating in seed treatments must: - wear the PPE required for handlers participating in seed treatments, - wear protective eyewear, if the closed system operates under pressure, and - be provided and have immediately available for use in an emergency, such as a spill or equipment malfunction, coveralls, chemical-resistant footwear, and the type of respirator required for handlers on this labeling." "When all other handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Environmental Hazards	"Environmental Hazards" "Do not apply directly to water, or to areas where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." *Surface Water Advisory* "Etridiazole can contaminate surface water through spray drift. Under some conditions, etridiazole may have a high potential for runoff into surface water for several weeks postapplication. These conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlaying tile drainage systems that drain surface water."	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval For WPS products as required by Supplement Three of PR Notice 93-7	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours." "INDOOR RESTRICTIONS: Entry (including early entry that would otherwise be permitted under the WPS) into greenhouses, potting sheds, and other indoor areas by any person -- other than a correctly trained applicator who is performing a handling task permitted by the WPS and who is wearing the required handler PPE including a respirator -- is PROHIBITED in the entire enclosed structure/building from the start of application until application is complete and one of the following ventilation criteria (providing outdoor air) is met: 10 air exchanges; (2) 2 hours of fans or other mechanical ventilation providing outdoor air; (3) 4 hours of vents, windows, or other passive ventilation; (4) 11 hours with no ventilation followed by 1 hour of mechanical ventilation; (5) 11 hours of no ventilation followed by 2 hours of passive ventilation; or (6) 24 hours with no ventilation. After ventilation criteria are met and until the REI expires, do not enter or allow worker entry into treated areas, except as provided in the WPS. Note: after the expiration of the REI whenever Terrazole-treated soil or planting media is being handled or disturbed indoors, continuous ventilation of the area is required at a minimum rate of one complete air exchange per hour.	

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Entry Restriction for non-WPS uses applied as a spray:	"Do not enter or allow others to enter until sprays have dried.	
Entry Restriction for non-WPS uses applied dry:	"Do not enter or allow others to enter until dusts have settled."	
Early Re-entry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice 93-7.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is:" For all end-use products: – Coveralls -- Chemical-resistant gloves such as or made out of any waterproof material -- Shoes plus socks	
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Do not allow this product to drift."	Place in the Direction for Use directly above the Agricultural Use Box.

Table 15. Summary of Labeling Changes for Etridiazole		
Description	**Labeling Changes**	**Placement on Label**
Other Use/Application Restrictions.	Labels must be modified to reflect the following restrictions: The maximum application rate for golf course tees and greens may not exceed 3.8 lbs. ai/A per application. The maximum amount applied to golf course tees and greens may not exceed 9.6 lbs ai/A per year. The interval between application to golf course tees and greens may not be less than 10 days. “Application to golf course turf is limited to tees and greens. Application to fairways is prohibited." “Application by hand-held broadcast spreader (belly grinder), push-type spreader, power dust blower, and dispersal by hand is prohibited.” (This only applies to formulations applied dry) “For dry soil mix, the maximum application rate for 3% ai granular products may not exceed 12 oz./cu.yd.” “For dry soil mix, the maximum application rate for 5% ai granular products may not exceed 8 oz./cu.yd.” “For commercial use only. Not for use on home lawns, sod farms, or municipal parks.” "For use in commercial greenhouses only. Use in residential greenhouses or other indoor plant sites is prohibited."	Directions for Use under General Precautions and restrictions and/or Applications Instructions

[1]PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.
[2]If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped. Instructions in the Required Labeling section appearing in quotations represent the exact language that must appear on the label.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; *Federal Register*, Volume 56, No. 123, June 26, 1991.

For etridiazole products registered for use on golf course turf:
The Agency and registrants have agreed that the registrants may distribute and sell the etridiazole end-use products bearing old labels/labeling until March 31, 2001. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

*For etridiazole products **except** those registered for use on golf course turf:*
The Agency has determined that registrants may distribute and sell etridiazole products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. Appendices

Appendix A. Use Patterns Eligible for Reregistration

Site Application Type	Formulation [EPA Reg. No.]	Max. Single Application Rate	Restricted Entry Interval	Plantback Interval[a]	Preharvest Interval	Use Limitations[b]
FOOD/FEED USES						
Barley, Peas, and Soybean						
Seed treatment	5% D [7501-54]	0.0125 lb. ai/bu	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5.8% RTU [7501-57]	0.0145 lb. ai/bu				
	5.8% EC [34704-679]	0.0145 lb. ai/bu				
Beans						
Seed treatment	5% D [7501-54]	0.00625 lb. ai/bu	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5.8% RTU [7501-57]	0.00725 lb. ai/100 lb. seed				
	5.8% EC [34704-679]	0.00725 lb. ai/bu				
Corn and Sorghum						
Seed treatment	5% D [7501-54]	0.0125 lb. ai/100 lb. seed	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5.8% RTU [7501-57]	0.00725 lb. ai/100 lb. seed				
	5.8% EC [34704-679]	0.00725 lb. ai/100 lb. seed				
Cotton						
Seed treatment	5% D [7501-54]	0.05 lb. ai/100 lb. seed	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops these crops.	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5.8% RTU [7501-57]	0.058 lb. ai/100 lb. seed				
	5.8% EC [34704-679]	0.058 lb. ai/100 lb. seed				

Site Application Type	Formulation [EPA Reg. No.]	Max. Single Application Rate	Restricted Entry Interval	Plantback Interval[a]	Preharvest Interval	Use Limitations[b]
In-furrow at-planting	1.63% G [400-408]	0.3 lb. ai/A	12 hours	120 days: root crops 30 days: leafy vegetables, small grains and other rotated crops	NA	Apply only at planting. Cotton foliage may not be used for livestock feed. Do not use with cotton seed previously treated with etridiazole.
	2.5% G [400-406]	0.3 lb. ai/A				
	2.5% G [264-319]	0.375 lb. ai/A				
	3.8% G [400-456]	0.38 lb. ai/A				
	4.3% EC [400-475]	0.275 lb. ai/A				
	5.8% EC [400-405]	0.37 lb. ai/A				
	44.3% EC [400-422]	0.2215 lb ai/A				
Peanuts						
Seed treatment	2.5% D [7501-111, 7501-153]	0.009 lb. ai/100 lb. seed	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5% D [7501-54]	0.0125 lb. ai/100 lb. seed				
	5.8% RTU [7501-57]	0.0145 lb. ai/100 lb. seed				
	5.8% EC [34704-679]	0.0145 lb. ai/100 lb. seed				
Safflower						
Seed treatment	5% D [7501-54]	0.0125 lb. ai/100 lb. seed	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5.8% RTU [7501-57]	0.0145 lb. ai/100 lb. seed				
	5.8% EC [34704-679]	0.0145 lb. ai/100 lb. seed				
Wheat						
Seed treatment	5% D [7501-54]	0.00625 lb. ai/bu	12 hours	120 days: root crops 30 days: leafy vegetables, small grains, other rotated crops	NA	Treated seed must not be used for or mixed with food or animal feed, or processed for oil.
	5.8% RTU [7501-57]	0.00625 lb. ai/bu				
	5.8% EC [34704-679]	0.00725 lb. ai/bu				

Site Application Type	Formulation [EPA Reg. No.]	Max. Single Application Rate	Restricted Entry Interval	Plantback Interval[a]	Preharvest Interval	Use Limitations[b]
NON-FOOD/FEED USES						
Non-Bearing Citrus						
Containerized seedlings, liners	40% WP [58185-10]	0.3 lb. ai/400 s.f.	12 hours	NA	2 years	
Non-bearing Coffee						
Seedlings (propagation)	40% WP [58185-10]	0.083 lb. ai/s.y.	12 hours	NA	2 years	
Golf Course Turf						
Tees, greens, fairways	30% EC [58185-5]	3.8 lb. ai/A	12 hours	NA	NA	Maximum amount applied per season may not exceed 9.6 lbs ai/acre. Interval between applications may not be less than 10 days.
	35% WP [400-416]	3.8 lb. ai/A				
	30% WP [58185-7]	3.8 lb. ai/A				
Ornamentals						
Shade trees, herbaceous plants, nonflowering plants, woody shrubs and vines soil drench, side-dress	3% G [58185-23]	0.011 lb. ai/lin. ft.	12 hours	NA	NA	Application with hand-held or push-type equipment, power dust blower and by hand is prohibited.
	5% G [58185-13]	0.0125 lb. ai/100 lin. ft.				
	25% EC [400-417]	0.125 lb. ai/400 s.f.				
	25% EC [58185-8]	0.125 lb. ai/400 s.f.				
	30% WP [58185-7]	0.225 lb. ai/400 s.f.				
	35% WP [400-416]	0.175 lb. ai/400 s.f.				
	40% WP [58185-10]	0.3 lb. ai/400 s.f.				
	44.3% EC [400-422]	0.111 lb./400 s.f.				

Site Application Type	Formulation [EPA Reg. No.]	Max. Single Application Rate	Restricted Entry Interval	Plantback Interval[a]	Preharvest Interval	Use Limitations[b]
Shade trees, herbaceous plants, nonflowering plants, woody shrubs and vines	3% G [58185-23]	0.0225 lb./c.y.	12 hours	NA	NA	
	5% G [400-419, 58185-13]	0.025 lb./c.y.				Application with hand-held or push-type equipment, power dust blower and by hand is prohibited.
dry soil mix	30% WP [58185-7]	0.05625/c.y.				
Tobacco						
transplant float beds	35% WP [400-416]	0.7 lb./100 gal.	12 hours	NA	NA	see Table 15 for details

[a]Plantback intervals are based on etridiazole rotational crop study and apply only to etridiazole. For products containing multiple active ingredients, plantback intervals for all active ingredients must be compared and the most protective interval will be applied.

[b]Refer to Table 15 of the *Reregistration Eligibility Document* for additional use restrictions.

Formulation Codes

D: Dust
EC: Emulsifiable concentrate
G: Granular
RTU: Liquid ready-to-use
WP: Wettable powder

Unit Descriptions

ai/bu: active ingredient per bushel
ai/A: active ingredient per acre
s.f.: square feet
lin. ft.: linear feet
c.y.: cubic yards
s.y.: square yards

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the case covered by this RED. It contains generic data requirements that apply etridiazole in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

    A. Terrestrial food
    B. Terrestrial feed
    C. Terrestrial non-food
    D. Aquatic food
    E. Aquatic non-food outdoor
    F. Aquatic non-food industrial
    G. Aquatic non-food residential
    H. Greenhouse food
    I. Greenhouse non-food
    J. Forestry
    K. Residential
    L. Indoor food
    M. Indoor non-food
    N. Indoor medical
    O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
Product Chemistry				
830.1550	61-1	Product identity and composition	all	43597401
830.1600	61-2(a)	Beginning materials and manufacturing process	all	00001553, 42912201
830.1620	158.162	Description of production process	all	00001553, 42912201
830.1670	61-2(b)	Formation of impurities	all	42912202
830.1700	62-1	Preliminary analysis	all	00158120, 42912203, 43597401
830.1750	62-2	Certification of limits	all	42912204
830.1800	62-3	Analytical method	all	00158120, 42912203, 43597401
830.6302	63-2	Color	all	00001553
830.6303	63-3	Physical state	all	00001553
830.6304	63-4	Odor	all	00001553
830.6313	63-13	Stability	all	00001553, 42912210, 42912211, 42912212
830.6314	63-14	Oxidizing/reducing action	all	42912213
830.6315	63-15	Flammability	all	00001553
830.6316	63-16	Explodability	all	00062469
830.6317	63-17	Storage stability	all	00001553, 43232001
830.6319	63-19	Miscibility	all	00062469

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
830.6320	63-20	Corrosion characteristics	all	00001553, 43232002
830.7000	63-12	pH	all	00001553
830.7050	none	UV/Visible absorption	all	**Data gap**
830.7100	63-18	Viscosity	all	42912214
830.7220	63-6	Boiling point	all	00001553
830.7300	63-7	Density	all	00001553
830.7370	63-10	Dissociation constant	all	42912209
830.7550	63-11	Octanol/water partition coefficient	all	42515901
830.7840 830.7860	63-8	Solubility	all	00001553, 00001644, 42912205, 42912206, 42912207
830.7950	63-9	Vapor pressure	all	00001553, 42912208
Environmental Fate				
835.1240	163-1	Leaching/adsorption/desorption	ABCI	43504302, 43504303, 43504304
835.1410	163-2	Volatility - laboratory	ABI	43024101
835.1850	165-1	Confined rotational crop	AB	44311401
835.2120	161-1	Hydrolysis	ABCIM	00001650
835.2410	161-3	Photodegradation - soil	AB	43124301
835.4100	162-1	Aerobic soil metabolism	ABCI	43504301

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
835.4400	162-3	Anaerobic aquatic metabolism	ABI	43504305
835.6100	164-1	Terrestrial field dissipation	ABC	44864901, 44689601 (supplemental), 44689602, 44689603
850.1730	165-4	Bioaccumulation in fish	ABC	43241401
Ecological Effects				
850.1010	72-2(a)	Invertebrate toxicity	ABCIM	**Data gap** 00062427 (supplemental)
850.1035	72-3(c)	Estuarine/marine toxicity - shrimp	ABC	42834603
850.1055	72-3(b)	Estuarine/marine toxicity - mollusk	ABC	42834602 (supplemental)
850.1075	72-1(b)	Fish toxicity - bluegill sunfish	ABCIM	0001773, 00001572 (supplemental)
850.1075	72-1(d)	Fish toxicity - rainbow trout	ABCIM	0001773, 00001572 (supplemental), 44606702
850.1075	72-3(a)	Estuarine/marine toxicity - fish	ABC	42834601
850.1400	72-4(a)	Early life stage - fish	ABC	42834604 (supplemental) 42834605
850.2100	71-1	Avian acute oral toxicity	ABCIM	00002238, 00003276 (supplemental)
850.2200	71-2(a)	Avian dietary toxicity - quail	ABCIM	00062478 (supplemental), 00062479 (supplemental)

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
850.2300	71-4(a)	Avian reproduction - quail	ABC	43744101 (supplemental), 43715601
850.2300	71-4(a)	Avian reproduction - duck	ABC	43744102 (supplemental), 43744103
850.4400	122-2	Aquatic plant growth	C	42834606, 42834607, 42834608, 42834609, 42834610 (supplemental)
Residue Chemistry				
860.1300	171-4(a)	Nature of residue - plants	ABM	00001689, 00028419, 00093751, 43940001, 44054701, 44285200, 44453201
860.1300	171-4(b)	Nature of residue - livestock	ABM	00093753, 00093754
860.1340	171-4(c)	Residue analytical method - plants	ABM	00001570, 00001645, 00002229, 00002239, 00002257, 00028423, 00028424, 00028428, 00014333, 00093752, 00139669
860.1340	171-4(d)	Residue analytical method - livestock	ABM	00001695, 00093752, 00093755
860.1360	171-4(m)	Multiresidue methods	AB	43259601
860.1380	171-4(e)	Storage stability	AB	00093754, 00093755, 44285001, 43305701
860.1500	171-4(k)	Crop field trials (cottonseed)	AB	00014318, 00028427, 00064191, 00064194, 44285901
860.1520	171-4(l)	Processed food/feed (cottonseed)	AB	00093755, 00093756, 00093747, 00093748, 44285901
Toxicology				

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
870.1100	81-1	Acute oral toxicity - rat	ABCIM	43724501
870.1200	81-2	Acute dermal toxicity - rabbit	ABCIM	43724502
870.1300	81-3	Acute inhalation toxicity - rat	ABCIM	43724503
870.2400	81-4	Primary eye irritaton - rabbit	ABCIM	43724504
870.2500	81-5	Primary dermal irritation - rabbit	ABCIM	43724505
870.2600	81-6	Dermal sensitization	ABCIM	43724506
870.3100	82-1(a)	90-day oral toxicity - rodent	ABCIM	**Data gap**
870.3150	82-1(b)	90-day oral toxicity - dog	ABCIM	**Data gap**
870.3200	82-2(b)	21/28-day dermal toxicity - rabbit	ABCIM	**Data gap**
870.3700	83-3(a)	Developmental toxicity - rat	ABCIM	00120415
870.3700	83-3(b)	Developmental toxicity - rabbit	ABCIM	00104999
870.3800	83-4	Multigeneration reproduction toxicity - rat	ABCIM	**Data gap**
870.4100	83-1(b)	Chronic oral toxicity - dog	ABCIM	**Data gap**
870.4200	83-2(a)	Oncogenicity - rat	ABCIM	40747901
870.4200	83-2(b)	Oncogenicity - mouse	ABCIM	**Data gap**
870.5100	84-2	Gene mutation - *S. typhimurium* and *E. coli*	ABCIM	**Data gap;** 00073206
870.5300	84-2	Gene mutation/*in vitro* mammalian cell assay in Chinese hamster ovary cells	ABCIM	00093743

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Etridiazole

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
870.5385	84-2(b)	Cytogenetics/*in vivo* mouse micronucleus assay	ABCIM	41837501
870.5900	84-2	Other mutagenic mechanisms/*in vitro* sister chromatid exchange in Chinese hamster ovary cells	ABCIM	00120414
870.5375/ 870.5900	84-2	Other mutagenic mechanisms/*in vitro* cytogenetics/sister chromatid exchange in Chinese hamster ovary cells	ABCIM	00120416
870.7485	85-1	Metabolism - rat	ABCIM	43654801
Occupational and Residential Exposure				
875.1100	231	Estimation of dermal exposure - outdoor (applicator)	ABC	43717901, 43666001 (supplemental)
875.1300	232	Estimation of inhalation exposure - outdoor (applicator)	ABC	43717901, 43666001 (supplemental)
875.2100	132-1(a)	Foliar residue dissipation (postapplication)	ABC	43287801 (supplemental), 43287802 (supplemental)
875.2200	132-1(b)	Soil residue dissipation (postapplication)	ABC	44227801 (supplemental), 43287801 (supplemental), 43287802 (supplemental)
875.2400	133-3	Dermal passive dosimetry (postapplication)	ABC	44227801 (supplemental), 43287801 (supplemental), 43287802 (supplemental)
875.2500	133-4	Inhalation passive dosimetry (postapplication)	ABC	44227801 (supplemental)

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The following documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at: www.epa.gov/pesticides/op

General

Overview of Preliminary Etridiazole (Terrazole®) Risk Assessment
Etridiazole (Terrazole®) Summary
Quantitative Usage Analysis for Etridiazole, June 15, 1999
Response to Registrant's 30-Day Comments on the Preliminary Risk Assessments, June 5, 2000
Notes of the Terrazole Mitigation Discussion, May 23, 2000

Human Health Assessment

Revised Human Health Risk Assessment, June 6, 2000
Appendices to the Health Effects Assessment, June 6, 2000
Report of the Hazard Identification Assessment Review Committee (HIARC), June 29, 1999
Report of the Hazard Identification Assessment Review Committee (HIARC), Requirement of a Carcinogenicity Study in a Second Species, the Mouse, July 26, 2000
HIARC Revisit to Estimate the Percentage (%) Dermal Absorption of the Fungicide, Terrazole, July 27, 2000
Report of the FQPA Safety Factor Committee, June 3, 1999
Acute and Chronic (Cancer and Non-Cancer) Dietary Exposure Analyses, November 29, 1999
Product and Residue Chemistry Chapters, November 17, 1999
Toxicology Chapter, December 23, 1999
Revised Toxicology Chapter, September 13, 2000
Revised Occupational and Residential Exposure Assessment, June 5, 2000

Ecological Risk Assessment

Revised Environmental Risk Assessment, May 22, 2000
Appendices to the Environmental Risk Assessment
Refined Tier 1 Chronic Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment, May 26, 2000

Appendix D. Citations Considered to Be Part of the Data Base Supporting the Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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Appendix E. Generic Data Call-In

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. Product-Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix G. EPA's Batching of Etridiazole Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing ***etridiazole (Terrazole®)*** as the primary active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note the Agency is not describing batched products as "substantially similar" since some products with in a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within in a batch, or to generate all the required acute toxicological studies for each of their own products. If the registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If the registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by to-days standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, the registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response, " asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing data (Option 1), Submitting an existing Study (Option 4), Upgrading an existing Study (Option 5), or Citing an Existing Study (Option). If a

registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twenty seven products were found which contain ***Terrazole*** as the active ingredient. These products have been placed into ***six*** batches and a ***"No Batch"*** category in accordance with the active and inert ingredients and type of formulation.

Batch 1	**EPA Reg. No.**	**Percent Active Ingredients**	**Formulation Type**
	400-423	43.0	Liquid
	58185-19	40.0	Liquid
	58185-20	40.0	Liquid

Batch 2	**EPA Reg. No.**	**Percent Active Ingredients**	**Formulation Type**
	400-416	35.0	Solid
	58185-5	32.3	Solid
	58185-7	30.0	Solid

Batch 3	**EPA Reg. No.**	**Percent Active Ingredients**	**Formulation Type**
	400-417	25.0	Liquid
	58185-8	25.0	Liquid

Note: *Formulations in Batch 4 may be cited to support acute toxicity data for product in Batch 4a.*

Batch 4	**EPA Reg. No.**	**Percent Active Ingredients**	**Formulation Type**
	400-419	5.35	Solid
	58185-13	5.0	Solid
Batch 4a	58185-16	1.3	Solid

Note: *Formulations in Batch 5 may be cited to support acute toxicity data for product in Batch 5a.*

Batch 5	**EPA Reg No.**	**Percent Active Ingredients**	**Formulation Type**
	400-405	5.8 Terrazole 23.0 PCNB	Liquid
	34704-679	5.8 Terrazole 23.0 PCNB	Liquid
Batch 5a	400-455	5.8 Terrazole 23.0 PCNB	Liquid

Batch 6	**EPA Reg. No**	**Percent Active Ingredients**	**Formulation Type**
	7501-111	2.5 Terrazole 10.0 PCNB 18.75 Maneb 18.00 Captan	Solid
	7501-153	2.5 Terrazole 10.0 PCNB 18.75 Maneb 18.00 Captan	Solid

Note: EPA Reg. No. 400-456 may be cited to bridge acute toxicity data for EPA Reg. No. 400-406.

No Batch	EPA Reg. No.	Percent Active Ingredients	Formulation Type
	264-319	2.5 Terrazole 5.0 Aldicarb 10.0 PCNB	Solid
	400-408	1.63 Terrazole 6.5 PCNB 6.5 Disulfoton	Solid
	400-475	4.3 Terrazole 17.5 PCNB 17.5 Disulfoton	Liquid
	58185-10	15.0 Terrazole 25.0 Thiophanate-methyl	Solid
	400-413	98.6 Terrazole	Liquid
	400-422	44.0 Terrazole	Liquid
	400-406	2.5 Terrazole 10.0 PCNB	Liquid
	400-456	3.86 Terrazole 15.0 PCNB	Solid
	7501-54	5.8 Terrazole 25.0 PCNB	Solid
	58185-23	3.0 Terrazole 5.0 Thiophanate-methyl	Solid
	7501-57	5.8 Terrazole 23.0 PCNB	Liquid

Appendix H. List of Registrants Sent This Data Call-In Notice

Appendix I. Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.

8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

a. Registration Division Personnel Contact List
2. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner

encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.